國立政治大學經營管理碩士學程
非營利組織管理組
碩士論文

指導教授：苑守慈博士

對多重利益相關者之意義提升是臨床醫療服務典範轉移的原因
—以某區域教學醫院主動脈瘤支架手術迅速普及之經驗為例

Newly defined meanings to multiple stakeholders are the reasons for paradigm shift in clinical medical service — experience from the rapid adoption of endovascular aortic repair in a regional hospital

研究生：謎大中
中華民國一百年七月

Dedicate to my Patients

Acknowledgement

Having been a cardiac and vascular surgeon for 14 years, it's not easy for me to look at things without a surgeon's point of view. During the past couple of months, I tried hard to avoid my surgeon's prejudice and to look at things with different point of views in preparing the thesis.

Professor Yuan's inspiring lectures on service science and innovation opened a door for me to the beauty of service science. Studies and preparation for the thesis offered me with the opportunity to regurgitate what I've learnt in the class.

Also, supports from my families, colleagues, and patients can never be overemphasized.

Lastly, I offer my regards and blessings to all of those who supported me in any respect during the completion of the project.

中文摘要

在現代外科實務中，我們今天認為是標準作業程序的手術，追溯到初期可能是激進創新。多年來，外科技術雖然已經有頻繁的修改，但往往是漸進式地。心臟和血管外科領域中的大多數創新並沒有導致日常實踐劇變。然而，在過去的幾年中，在我服務的醫院和全世界，我看到了治療腹主動脈瘤（AAA）的典範轉移，亦即主動脈腔內修復（EVAR）。

相對於傳統開腹手術修復 （OSR），主動脈腔內修復較傳統開腹手術修復有顯著較低的手術死亡率。不過，長遠來說，總死亡率或動脈瘤相關死亡率並無差異；而主動脈腔內修復有較高的植入物相關併發症和必須再次手術的機率，且成本更高。然而，主動脈腔內修復還是成為腹主動脈瘤治療的支柱。這是為什麼？

除了是激進的技術創新，主動脈腔內修復也是技術頓悟。傳統上，醫療服務是典型的技術輔助服務情境，其中包含兩個單獨的、然而是密切相關的溝通系統：一個是產業與醫師之間，另一個是醫師與病人之間。醫師居於樞紐地位，不僅確保治療之執行，而且還要評估結果。由於現代資訊與通信技術的發達，病人可以方便地搜尋輔助醫療文獻資訊、線上資訊和個人社會網絡的意見。這就像是詮釋者的作用。這詮釋者的解釋對病人、外科醫生、和醫療產業界產生了實質上重大的影響，反之亦然。以前在這服務體系中互相分離的部分現在可以緊密地互相配合了，這與服務導向邏輯中價值共同創造的概念是不謀而合的。

總之，對多重利益相關者之意義提升是臨床醫療服務典範轉移的原因。在醫療行業中引入服務導向邏輯的概念的重要性，不論是在日常實務和創新策略上的意義都是不容忽視的。醫療服務中，多重利益相關者比以前更涉及共同創造價值的過程。未來的創新者除了專注在技術和科技上，更必須考慮該創新對多重利益相關者之意義提升。

Abstract

In modern surgical practice, what we consider as standard procedures today may be radical innovations dated back to the early days. Over the years, there has been frequent modification of surgical techniques, often incremental though, and most innovations in the field of cardiac and vascular surgery didn't result in drastic changes in the daily practice. However, during the past several years, I have been witnessing a paradigm shift in the treatment of abdominal aortic aneurysm (AAA) in my hospital and worldwide towards endovascular aortic repair (EVAR).

In comparison to the traditional open surgical repair (OSR), EVAR was associated with a significantly lower operative mortality than OSR. However, no differences were seen in total mortality or aneurysm-related mortality in the long term, and EVAR was associated with increased rates of graft-related complications and reinterventions and was more costly. Nevertheless, EVAR is becoming the mainstay of AAA treatment. Why is this?

Except for being a radical technology innovation, EVAR is also a technology epiphany. Traditionally, medical service is a typical technology-assisted service encounter, consisting of two separate, however, closely inter-related communication systems: one between the industry and the physician, and the other one between the physician and the patient. The physician is of the pivot role that not only ensures the execution of treatment but also evaluates the results. With modern information and communication technologies, patients can easily search information from paramedical literatures, online information, and opinions from personal social network. This serves the emerging role of an interpretor. This interpretors' interpretation has substantial influence on patients, surgeons, industry, and payers and vice versa. Previously separated parts in the service system now can be closely inter-related. This is in concordance with the concept of co-creation of value in service-dominant logic.

It is concluded that newly defined meanings to multiple stakeholders are the reasons for paradigm shift in clinical medical service. The importance of introduction of the concept of service-dominant logic into the medical industry, both in daily practice and in innovation strategy can never be over-emphasized. Multiple stakeholders are being involved much more than before in the process of co-creation of value in medical service. Future innovators must concentrate on meanings to multiple stakeholders as well on techniques and technologies.

Table of Contents

List of Tables

List of figures

Chapter I

Introduction

1.1 Motivation of the Study

The author has been a cardiovascular surgeon for 14 years. I do a lot of surgeries in my daily practice, including coronary artery bypass surgery, heart valve surgery, peripheral vascular surgery, and aortic surgery. What we consider as standard procedures today may be radical innovations dated back to the early days. Take cardiopulmonary bypass which is a routine and essential part of modern open heart surgery as an example. Between March 26, 1954 and July 19, 1955, C. Walton Lillehei and colleagues operated upon 45 infants and children with previously uncorrectable cardiac anomalies using cross-circulation with a human donor. The concept of cross-circulation represented "the dawn of open-heart surgery" (Moller, Shumway, & Gott 2009). This concept contributed to the invention of heart-lung machine (cardiopulmonary bypass) that soon followed.

Over the years, there has been frequent modification of surgical techniques, often incremental though. Of course, there were major radical innovations, like off-pump coronary artery bypass surgery, robotic mitral valve repair, and etc. Not any one of them has gained wide acceptance. For example, since its advent some 20 years ago, only 20% of patients were operated on with off-pump technique, while the remaining 80% of patients accepted traditional surgery. Most innovations in the field of cardiac and vascular surgery didn’t result in drastic changes in the daily practice.

During the past two years, I have been witnessing a paradigm shift in the treatment of abdominal aortic aneurysm in my hospital. Endovascular aortic repair (EVAR) is a new and less invasive surgery in comparison to open surgical repair

(OSR) as a treatment modality to abdominal aortic aneurysm. In my hospital, we started EVAR program in 2009, and amazingly it soon became the mainstay of treatment within 1 year. This rapid acceptance and dissemination of EVAR not only has been observed in my hospital, but also it has been a worldwide trend. What are the underlying reasons for this phenomenon of radical innovation? It's the aim of this study to figure them out.

1.2 Research Objectives and Questions

This study is focused on the process of rapid adoption of an innovatively new endovascular aortic repair (EVAR) technique to treat abdominal aortic aneurysm within one year in a 750-bedded regional hospital in New Taipei City. At the same time span, the numbers of traditional open aortic repair procedures decreased dramatically. Since most innovations in surgical techniques are incremental, this observed phenomenon is quite unique and exceptional. The research objectives are therefore to explore the underlying contributing reasons for this phenomenon.

The author tried to answer the following questions:

1. What is the reason for the paradigm shift in the treatment of abdominal aortic aneurysm in this certain period of time?
2. Is there a specific innovation model in the transformation process from traditional open surgery to modern less invasive surgery?

1.3 Research Flow and Chapter Description

This study flow started with the research motivation and objectives, followed by literature review. Related research works and literatures from both the medicine and the business study field were reviewed to formulate the theoretical bases of this service and innovation study. There were two parts of the following case study. First

part of the case study consisted of an analysis of medical records of all patients with abdominal aortic aneurysm treated either with traditional open surgery or with EVAR in the case hospital in the study period. The results concerning the medical and the financial aspects were analyzed. The second part of the case study consisted of an in-depth interview of two surgeons and seven industry persons. The interview results were analyzed for meanings. Compiling the results from the literatures reviewed and conjectures deduced from those observed facts in the case study, an explanatory conclusion was achieved.

This thesis is divided into five chapters: the introduction, review of literatures, research methodology, case description and analysis, and conclusions and future perspectives.

1.4 Research Scope and Limitation

The author intends to figure out the reasons underlying the process of a certain radical innovation in the case hospital through case study and in-depth interview. The conclusions are theoretically valid only concerning the case hospital in this limited period of time. However, as a service and innovation study, I hope there is a category effect — the conclusions could be extrapolated to similar categories of medical service and innovations.

Of course, there must be imperfections in the analysis and conclusions. Future studies are needed to answer those remaining questions.

Chapter II

Review of Literature

This is a service and innovation study in which conclusions are deduced from facts directly observed in daily medical practice or from comprehensive review of literatures. Related research works and literatures from both the medicine and the business study field were reviewed to formulate the theoretical bases of this service and innovation study.

We first briefly introduced the pathophysiology of abdominal aortic aneurysm and choices of treatment, focusing on the traditional open surgical repair and the innovative endovascular repair (2.1), followed by comparison of the two different treatment modalities concerning clinical results and cost-effectiveness (2.2). How patients make decision on treatment modality can be found from review of literatures on patients' decision-making process (2.3). In section 2.4 and 2.5, the innovation and dissemination process of endovascular repair are thoroughly discussed about.

2.1 Abdominal Aortic Aneurysm (AAA)

2.1.1 Introduction of Abdominal Aortic Aneurysm

Gloviczki, and Ricotta, (2011) wrote in Textbook of Vascular Surgery that the term aneurysm is derived from the Greek word aneurysma which means "widening" and can be defined as a permanent and irreversible localized dilation of a blood vessel, having at least a 50% increase in diameter compared with the expected normal diameter. Ectasia is defined as a dilation less than 50% of the normal diameter. Normal diameter of the aorta and the arteries depends on age, gender, body size, and

other factors. In men, the infrarenal aorta is normally between 14 and 24 mm, and in women, it is between 12 and 21 mm. Therefore, an abdominal aortic aneurysm (AAA) is diagnosed if the diameter is 3 cm or larger in a man or 2.6 cm or larger in a woman.

The most frequent site of extracranial arterial aneurysms is the infrarenal aorta. In one large autopsy series of patients with aortoiliac aneurysms, the most frequent location was the abdominal aorta alone (65%), followed by the thoracic aorta alone (19%), the abdominal aorta and iliac arteries (13%), the thoracoabdominal aorta (2%) and iliac arteries alone (1%). Peripheral arterial aneurysms are much less common. Popliteal aneurysms account for about 70% of all peripheral aneurysms, femoral aneurysms are less frequent, and carotids constitute less than 4%. Visceral (splanchnic) and renal artery aneurysms have been considered rare, although their reported incidence due to frequent abdominal imaging has increased recently. Fig. 2.1 demonstrated the anatomy of AAA.

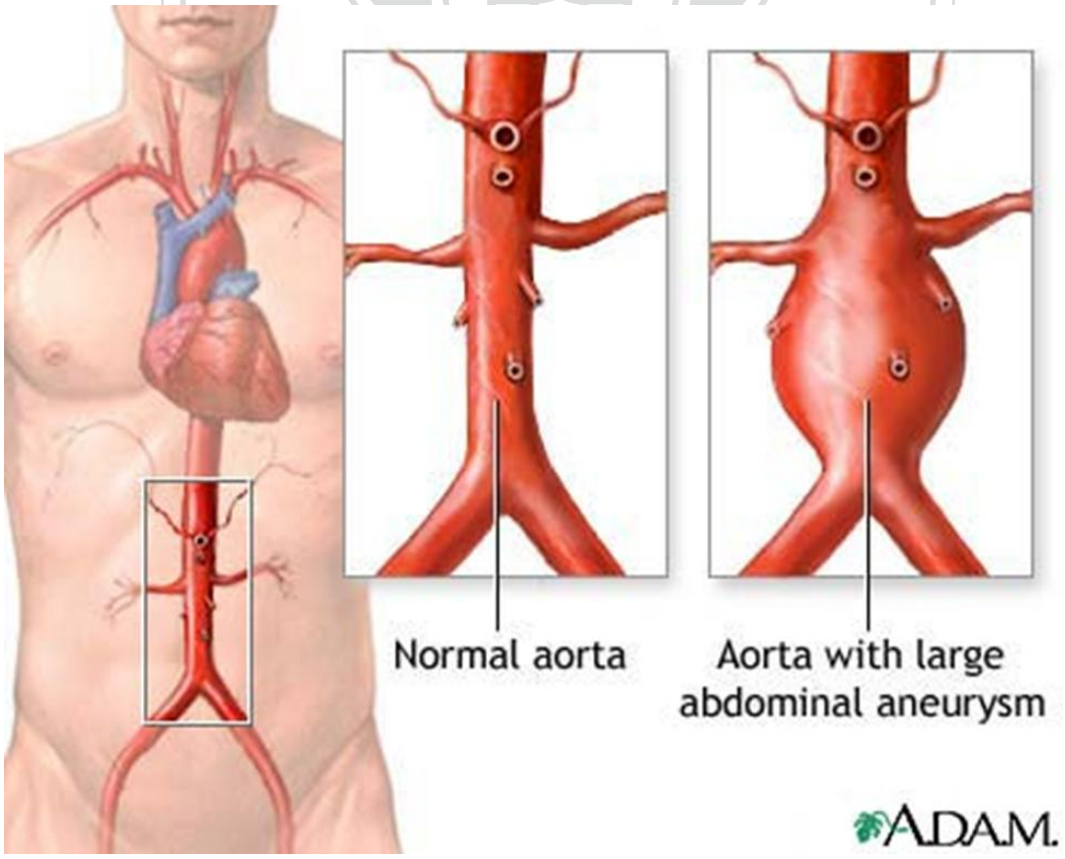

Figure 2.1 Illustration of abdominal aortic aneurysm. (source: “MedlinePlus”)

The natural history of AAAs is continuous expansion. Rupture is the most frequent and lethal complication of AAAs. In the United States, aneurysm rupture is the cause of death in 1.2% of men and 0.6% of women. About 15,000 deaths each year are caused by ruptured AAAs, making AAA the 13th leading cause of death in the United States. It is the 10th leading cause of death in men. In a study of 231 ruptured aneurysms, 71% of patients did not know before rupture that they had an aneurysm. Most ruptures occur into the retroperitoneal space, but free rupture of the anterior wall can result in herald bleeding into the abdominal cavity; rupture into the inferior vena cava or iliac vein causes aortocaval or aortoiliac arteriovenous fi stula, whereas rupture into the duodenum results in massive gastrointestinal bleeding due to a primary aortoduodenal fistula.

After rupture of an AAA, only half of patients arrive at the hospital alive. In one study, 50% reached the hospital alive, 7% died before surgery, 17% died during the operation, and 37% died within 30 days of surgery for an overall mortality rate for open surgical repair of 45%. Although initial results of EVAR for ruptured AAA have been encouraging, about 25% to 30% of patients with a ruptured AAA will eventually survive. Occasionally, AAAs can lead to life- and limb-threatening conditions because of acute thromboembolism.

The larger the aneurysm diameter is, the greater the risk for rupture is. The annual risk for rupture of an AAA between 4 and 5.4 cm in size is about 0.5% to 1%. For AAAs between 5.5 and 6 cm, the annual rupture risk is estimated between 5% and 10%. AAAs between 6 and 7 cm have an estimated yearly rate of rupture of 10% to 20%.

In 2003, a consensus statement was issued by the Society for Vascular Surgery regarding screening for AAAs. It recommended baseline ultrasound screening for AAA in men aged 60 to 85 years, women 60 to 85 years with cardiovascular risk

factors, and men and women older than 50 years with a family history of AAA. Subsequent ultrasound is recommended annually for AAAs 4.0 to 4.5 cm and every 6 months for AAAs larger than 4.5 cm. The United States approved the Screening Abdominal Aortic Aneurysms Very Efficiently (SAAAVE) Act to provide AAA screening at age 65, for male ever-smokers and men and women with a family history of AAA, as recommended by the U.S. Preventive Services Task Force.

For patients with low-risk AAAs (small diameter without other risk factors for rupture) being followed with serial size measurements, attempts are made to reduce expansion rate and rupture risk. This can be accomplished with risk factor modifications, including smoking cessation, blood pressure control, and reduction of cholesterol, triglycerides, and lipoproteins.

The goal of elective AAA repair is to prevent rupture and prolong life. Careful assessment of factors that influence rupture risk, operative mortality, and life expectancy is essential, and patient preference receives increasing importance.

2.1.2 Open Surgical Repair (OSR)

For open repair, several exposures can be used, each with its own merits and disadvantages. Options include a transperitoneal approach, through a long midline incision or through a mini-laparotomy, or the retroperitoneal approach through a left flank incision. Though the incisions and exposures may vary, the aim of the operation is to exclude or resect the aneurysmally dilated abdominal aorta and to replace it with a straight or a bifurcated graft.

If the iliac arteries are not aneurysmal, a straight collagen or gelatin-coated zero porosity polyester (Dacron) graft is used for repair, usually 16 or 18 mm in diameter. Both proximal and distal anastomoses are performed with 3-0 polypropylene running sutures. When the common iliac arteries are involved, a 16- or 18-mm bifurcated graft

is used and sutured to the distal common iliac arteries in an end-to-end fashion, using 4-0 polypropylene running sutures (Fig. 2.2).

Early mortality for open elective AAA repair has greatly improved during the past 2 decades because of improvements in preoperative evaluation, intraoperative techniques, and perioperative care. Mortality rates of elective open infrarenal AAA repair in good-risk patients can be expected to be less than 5%; in high-volume centers, the mortality rate is between 1% and 3%. (Rutherford 2004)

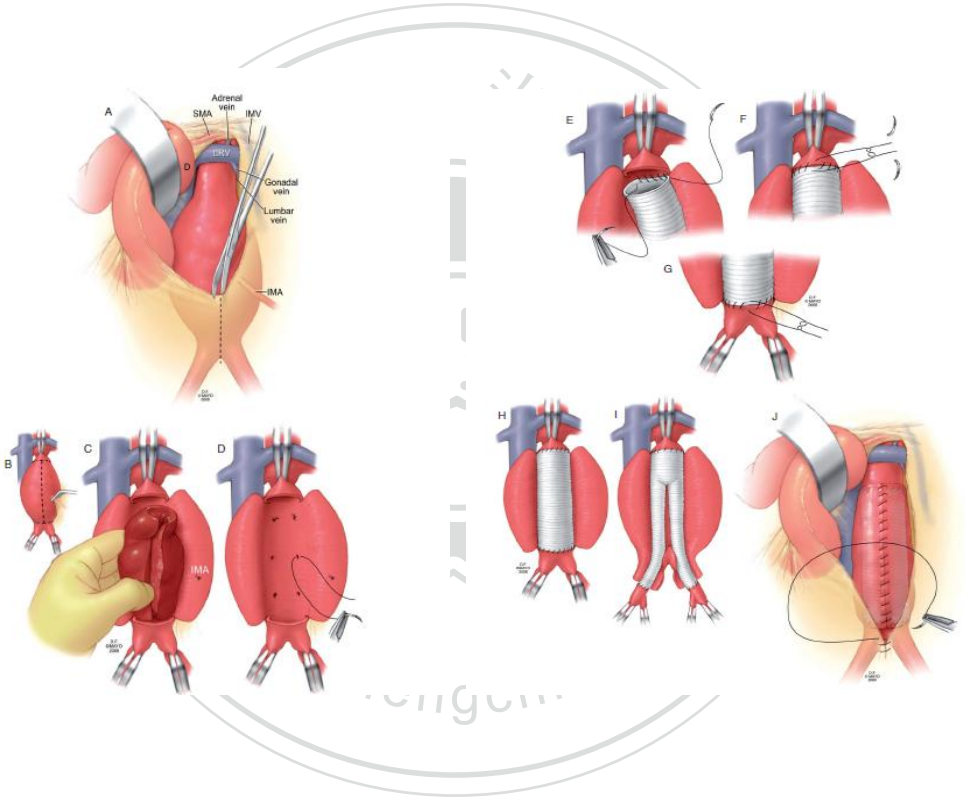

Figure 2.2 Operative techniques of trasnperitoneal abdominal aortic aneurysm repair with a straight or a bifurcated prosthetic graft. (source: Sabiston Textbook of Surgery, 18th Edition)

The 2003 Guidelines for the treatment of abdominal aortic aneurysms published by the Joint Council of the Vascular Societies noted that treatment of AAAs is individualized and recommended operative repair for AAAs with a diameter of 5.5 cm or greater in men. Those aneurysms that expand at a rate of more than 1 cm/year or that are symptomatic must be repaired. However, subsets of younger, low-risk patients, with long projected life expectancy, may prefer earlier repair. If the surgeon's operative mortality rate is low, repair may be indicated at smaller sizes (4.5-5.4 cm) if that is the patient's preference. For women and patients with a greater than average rupture risk, an AAA diameter of 4.5 to 5.0 cm is an appropriate threshold for elective repair. Atypical aneurysms (dissecting, pseudoaneurysms, mycotic, saccular, and penetrating ulcers) may be an indication for surgical treatment regardless of size. For high-risk patients, delay in repair until larger diameter is warranted, especially if EVAR is not possible. The guidelines recommended EVAR as the most appropriate option for patients at increased risk with conventional open repair. EVAR is preferred for older, high-risk patients; those with "hostile" abdomens; and patients with other clinical circumstance likely to increase the risk of open repair, if their anatomy is appropriate. It was emphasized that patient preference is of great importance.
It is essential that the patients be well informed to make such choices.

2.1.3 Endovascular Aortic Repair (EVAR)

In contrary to open surgical repair, in which the aneurysm is resected and the aorta was replaced with a prosthesis graft through a generous laparotomy or a flank incision, during EVAR, the stent-graft of which the mechanism of treatment is to exclude the blood from flowing into the aneurysm sac is introduced into the aneurysm through the femoral arteries and fixed in place to the nonaneurysmal aortic neck and iliac arteries with self-expanding or balloon-expandable stents. Some of the

stent-grafts have barbs, pins, or hooks to secure the stent, whereas some others have suprarenal fixation with self-expanding stents. A major abdominal incision is thus avoided, and procedure-related morbidity is reduced. An endovascular stent-graft excludes the aneurysm from blood flow and extends from the infrarenal aorta to both common iliac arteries, preserving flow to the internal iliac arteries.

This procedure can be performed in a surgery-capable catheterization laboratory or a surgical suite equipped with a fixed or mobile angiography C-arm. This can be performed under general, regional, spinal, or local anesthesia. Both common femoral arteries are cannulated either percutaneously or more commonly with femoral artery cutdowns. Vascular sheaths are placed over guidewires under fluoroscopic guidance into both external iliac arteries. The patient is systemically heparinized, and a diagnostic aortogram is performed through a marker pigtail catheter placed just above the renal arteries. Appropriate measurements are taken. Super-stiff guidewires are then inserted into the thoracic aorta through both femoral sheaths. The endograft device is advanced into the aorta, usually through its own deployment sheath. A multi-sidehole catheter is advanced from the contralateral side to mark the level of the renal arteries, and the main body device is deployed just below the lowest renal artery. Distally, it is deployed to just above the iliac bifurcation, taking care not to cover the hypogastric artery unless preoperatively planned. The contralateral limb gate is then cannulated, and an appropriately chosen contralateral iliac limb endograft device is deployed from within the main device to just above the iliac bifurcation. Balloon dilation is performed of all attachment sites, and completion angiogram is done with attention paid to position and sealing of the graft attachment sites.

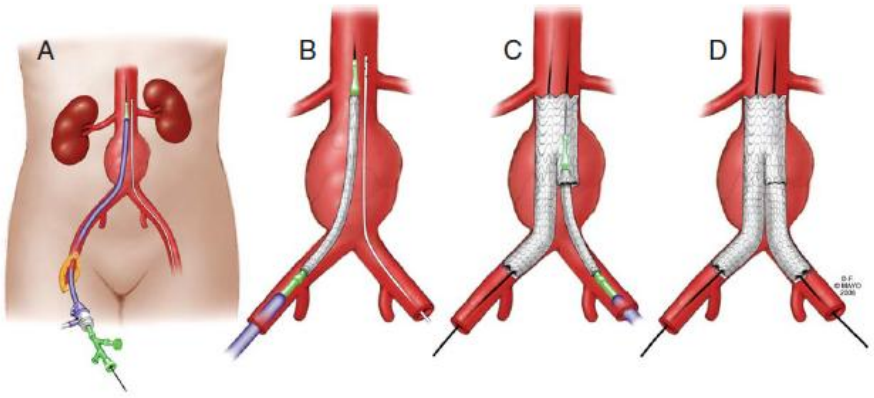

Figure 2.3 Techniques of endovascular aortic repair. (source: Sabiston Textbook of Surgery, 18th Edition)

2.2 Evaluation of Different Treatment Modalities

2.2.1 Clinical Results of Different Treatment Modalities

Since the advent of endovascular aortic repair techniques for surgical treatment of abdominal aortic aneurysm in the early 1990's, many meticulous amendments of the implantation techniques and a lot of technological improvement of endovascular stentgrafts have been observed. There are many clinical studies focusing on the short-term and long-term results of EVAR in comparison to OSR.

Within 10 years, Seelig (1999) reported in Mayo Clinic Procedings that in light of the potential to reduce morbidity and mortality associated with open surgical repair, endoluminal grafting offers therapeutic options to patients who are not surgical candidates because of comorbidities.

The United Kingdom EVAR Trial Investigators published the trial result in New England Journal of Medicine in 2010. From 1999 through 2004 at 37 hospitals in the United Kingdom, they randomly assigned 1252 patients with large abdominal aortic aneurysms (≥5.5 cm in diameter) to undergo either endovascular or open repair; 626 patients were assigned to each group. Patients were followed for rates of death,

graft-related complications, reinterventions, and resource use until the end of 2009. Logistic regression and Cox regression were used to compare outcomes in the two groups. The 30-day operative mortality was 1.8% in the endovascular-repair group and 4.3% in the open-repair group (adjusted odds ratio for endovascular repair as compared with open repair, 0.39; 95% confidence interval [CI], 0.18 to 0.87; P = 0.02). The endovascular repair group had an early benefit with respect to aneurysm-related mortality, but the benefit was lost by the end of the study, at least partially because of fatal endograft ruptures (adjusted hazard ratio, 0.92; 95% CI, 0.57 to 1.49; P = 0.73). By the end of follow-up, there was no significant difference between the two groups in the rate of death from any cause (adjusted hazard ratio, 1.03; 95% CI, 0.86 to 1.23; P = 0.72). (Fig. 2.4) The rates of graft-related

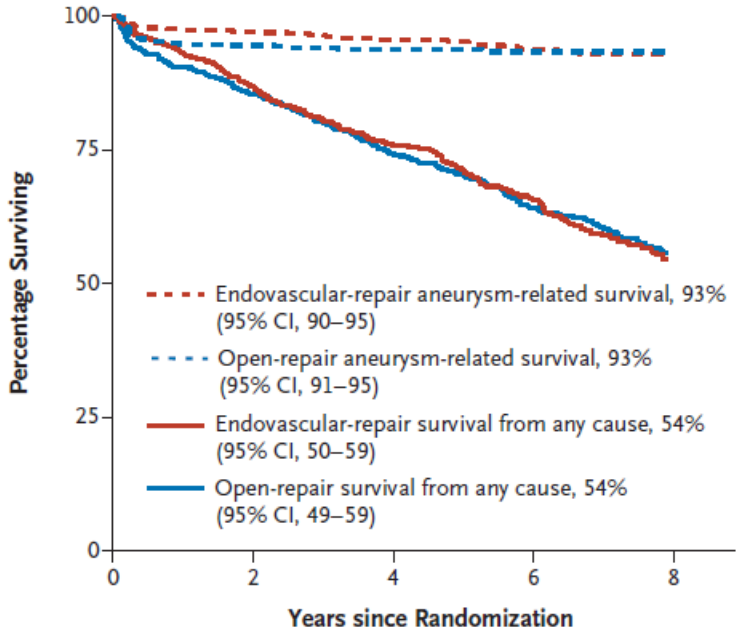

Figure 2.4 Kaplan–Meier Estimates for Total Survival and Aneurysm-Related Survival during 8 Years of Follow-up. (source: United Kingdom EVAR Trial Investigators 2010.)

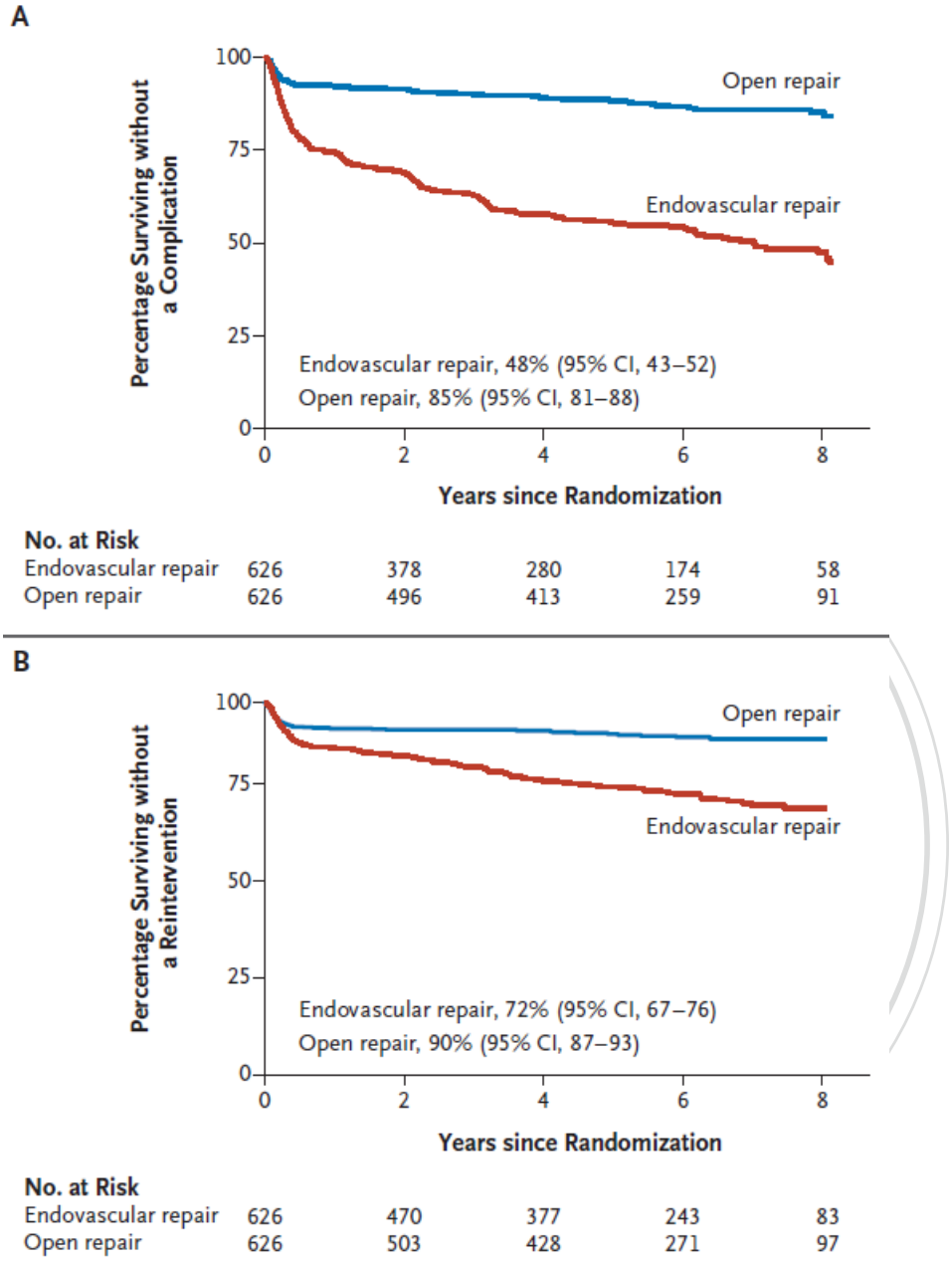

Figure 2.5 Kaplan–Meier Estimates for the Time to the First Graft-Related Complication or Reintervention during 8 Years of Follow-up. (source: United Kingdom EVAR Trial Investigators 2010.)

complications and reinterventions were higher with endovascular repair, and new complications occurred up to 8 years after randomization, contributing to higher overall costs. (Fig. 2.5) They concluded in this large, randomized trial, that

endovascular repair of abdominal aortic aneurysm was associated with a significantly lower operative mortality than open surgical repair. However, no differences were seen in total mortality or aneurysm-related mortality in the long term. Endovascular repair was associated with increased rates of graft-related complications and reinterventions and was more costly.

The United Kingdom EVAR Trial Investigators also published in New England Journal of Medicine in 2010 data on the question of whether endovascular repair reduces the rate of death among patients who were considered to be physically ineligible for open surgical repair. From 1999 through 2004 at 33 hospitals in the United Kingdom, they randomly assigned 404 patients with large abdominal aortic aneurysms (≥5.5 cm in diameter) who were considered to be physically ineligible for open repair to undergo either endovascular repair or no repair; 197 patients were assigned to undergo endovascular repair, and 207 were assigned to have no intervention. Patients were followed for rates of death, graft-related complications and reinterventions, and costs until the end of 2009. Cox regression was used to compare outcomes in the two groups. The 30-day operative mortality was 7.3% in the endovascular-repair group. The overall rate of aneurysm rupture in the no-intervention group was 12.4 (95% confidence interval [CI], 9.6 to 16.2) per 100 person-years. Aneurysm-related mortality was lower in the endovascular-repair group (adjusted hazard ratio, 0.53; 95% CI, 0.32 to 0.89; P = 0.02). This advantage did not result in any benefit in terms of total mortality (adjusted hazard ratio, 0.99; 95% CI, 0.78 to 1.27; P = 0.97). A total of 48% of patients who survived endovascular repair had graft-related complications, and 27% required reintervention within the first 6 years. During 8 years of follow-up, endovascular repair was considerably more expensive than no repair (cost difference, £9,826 [U.S. $14,867]; 95% CI, 7,638 to 12,013 [11,556 to 18,176]). The concluded that patients who were physically ineligible for

open repair, endovascular repair of abdominal aortic aneurysm was associated with a significantly lower rate of aneurysm-related mortality than no repair. However, endovascular repair was not associated with a reduction in the rate of death from any cause. The rates of graft-related complications and reinterventions were higher with endovascular repair, and it was more costly.

2.2.2 Cost-effectiveness of Different Treatment Modalities

We know from the previous section on clinical result that endovascular aortic repair is more costly that open surgical repair. Yet, we still don't know the cost-effectiveness and quality of life issue.

Young (2010) reported in the Journal of Vascular surgery an evaluation of the cost-effectiveness of endovascular repair (EVAR) for small abdominal aortic aneurysms (AAA). Outcomes were reported as quality-adjusted life-years (QALYs). The model demonstrated that early EVAR for 4.0 cm-5.4 cm AAAs led to fewer QALYs at greater costs when compared with observational management with elective repair at 5.5 cm. With a >70% probability, observational management until AAA diameter is 5.5 cm will be the cost-effective option. However, EVAR for small AAAs may become cost-effective when differences in quality of life and mortality are considered.

When EVAR was compared with OSR, Blackhouse's group reported in 2008 and 2009 that based on commonly quoted willingness-to-pay thresholds, EVAR was not found to be cost-effective compared to OSR. EVAR may be a cost-effective strategy compared with OSR for high-risk patients. Longer-term data are needed to decrease the uncertainty associated with the results.

In Chambers' review paper (2009), they concluded that open repair is more likely to be cost-effective than EVAR on average in patients considered fit for open

surgery. EVAR is likely to be more cost-effective than open repair for a subgroup of patients at higher risk of operative mortality. These results are based on extrapolation of mid-term results of clinical trials. Evidence does not currently support EVAR for the treatment of ruptured aneurysms. Further follow-up of the existing UK trials should be undertaken and the relative costs of procedures and devices should be investigated further.

2.3 Factors Influencing Choice of Treatment

Every clinician has been taught and trained to consider a patient's best benefit as the first priority. Can this aim be always achieved? This has been and still will be true for a certain percentage of clinical scenarios: one ill, one pill, and one bill. A patient was prescribed with a pill to treat a disease by a physician who was compensated for the treatment. However, as medical knowledge and technology are progressing explosively, not only patients but also clinicians are more frequently encountering puzzling clinical situations that can oftentimes be managed with more than one treatment modalities, of which each treatment modality carries its specific anticipated results, at the tradeoff of potential side-effects and complications, of course.

Is there always a straight forward best solution? If there is, who's going to make the decision out of the complex clinical situation? Is it easy for a patient to choose the best treatment modality for him/herself? Is it EVAR, OSR, or watchful waiting?

2.3.1 Shared Decision Making Model

Shared decision making is an approach where clinicians and patients communicate together using the best available evidence when faced with the task of making decisions, where patients are supported to deliberate about the possible attributes and consequences of options, to arrive at informed preferences in making a

determination about the best action and which respects patient autonomy, where this is desired, ethical and legal.

One of the first instances where the term ‘shared decision making’ was used was in a report entitled the ‘President's Commission for The Study of Ethical Problems in Medicine and Biomedical Research. (President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, 1998). This work built on the increasing interest in patient-centredness and an increasing emphasis on recognising patient autonomy in health care interactions since the 1970s.

Shared decision-making is increasingly advocated as an ideal model of treatment decision-making in the medical encounter. The particular decision-making context that we focus on is potentially life threatening illnesses, where there are important decisions to be made at key points in the disease process, and several treatment options exist with different possible outcomes and substantial uncertainty. Charles et al. (1997) suggested as key characteristics of shared decision-making (1) that at least two participants—physician and patient be involved; (2) that both parties share information; (3) that both parties take steps to build a consensus about the preferred treatment; and (4) that an agreement is reached on the treatment to implement.

In December 2010 a Salzburg Global Seminar focused on "The Greatest Untapped Resource in Healthcare? Informing and Involving Patients in Decisions about Their Medical Care." Powerful conclusions emerged among the 58 participants from 18 countries: not only is it ethically right that patients should be involved more closely in decisions about their own medical care and the risks involved, it is practical – through careful presentation of information and the use of decision aids/pathways – and it brings down costs. Unwarranted practice variations - where one area may have many more interventions than another, but with no better outcomes – are reduced, sometimes dramatically.

Do patients really want to participate in decision making? Levinson et al. (2004) reported in their population-base study that people vary substantially in their preferences for participation in decision making. Physicians and health care organizations should not assume that patients wish to participate in clinical decision making, but must assess individual patient preferences and tailor care accordingly.

Patients may wish to participate in a variety of ways including seeking and exchanging information, discussing options in care, and making the final decisions about treatment. Patients who are active participants in the process of their care may have improved medical outcomes. To this end, consumer groups and medical organizations alike encourage patients to engage in making decisions in collaboration with their physicians.

Yet, not all patients want to participate to the same degree. Some may wish to be active in discussing treatment options but may ultimately want to rely entirely on their physicians to make decisions on their behalf. Nearly all respondents (96%) preferred to be offered choices and to be asked their opinions. In contrast, half of the respondents (52%) preferred to leave final decisions to their physicians and 44% preferred to rely on physicians for medical knowledge rather than seeking out information themselves. Women, more educated, and healthier people were more likely to prefer an active role in decision making. African-American and Hispanic respondents were more likely to prefer that physicians make the decisions. Preferences for an active role increased with age up to 45 years, but then declined.

2.3.2 Impact of Online Information on Decision Making

When diagnosed with an abdominal aortic aneurysm (AAA), patients are confronted with a complex decision: whether or not to undergo invasive treatment for an asymptomatic but potentially fatal condition. Effective communication of this

information during the informed consent process can be challenging because of the volume and complexity of the information involved as well as the emotional impact of the potentially life-changing alternatives being considered. Many patients neither appreciated the scope of their options before AAA repair nor felt adequately informed prior to making a decision.

The internet has the potential to provide patients with information and support as an adjunct to direct communication with the surgeon. Nevertheless, Goldberg, Berman, and Gusberg, (2010) suggested that websites frequently accessed by patients lack important information regarding surgical risk. The most common risk reported was mortality, which was reported by less than one-third of sites as a risk for open repair and less than 10% of sites as a risk for EVAR. Within the discussion of risks, few sites quantified the probability that a complication would occur. When EVAR was presented as an alternative to open surgery, they found that websites tended to present more information about the benefits and less information about the risks of EVAR. Less than 20% reported a risk of reintervention after EVAR. Although 40% of sites alluded to the concept of increased follow-up after EVAR, only 18.5% specified the need for annual CT scans. Reporting of surgical risk was even lower among industry-sponsored websites.

The lack of information available to patients has important implications for the physician-patient encounter. Even proactive patients who are seemingly wellinformed may lack important information about health risk. Patients who form treatment preferences based on information obtained online are likely to have based these preferences on incomplete and possibly misleading information about the treatment options and their risks, potentially leaving them with unrealistic expectations of outcomes. Assessing the degree to which patients are making informed choices requires an understanding of the adequacy of information obtained from the internet

and patients' ability to interpret this information. Surgeons and other physicians who regularly discuss AAA management options with their patients should be aware of the potential for patients to arrive with preconceived notions based on what they have read online and be prepared to provide more complete information on risk and outcomes.

2.3.3 Service-dominant Logic and Co-creation of Value

Can the medical society borrow any idea from the business world?

Vargo and Lusch (2004) suggested "increasingly, marketing has shifted much of its dominant logic away from the exchange of tangible goods (manufactured things) and toward the exchange of intangibles, specialized skills and knowledge, and processes (doing things for and with), which we believe pints marketing toward a more comprehensive and inclusive dominant logic, one that integrates goods with services and provides a richer foundation for the development of marketing thought and practice."

The service-centered view of marketing implies that marketing is a continuous series of social and economic processed that is largely focused on operant resources with which the firm is constantly striving to make better value propositions than its competitors. In a free enterprise system, the firm primarily knows whether it is making better value propositions from the feedback it receives from the marketplace in terms of firm financial performance. Because firms can always do better at serving customers and improving financial performance, the service-centered vie of marketing perceives marketing as a continuous learning process (directed at improving operant resources).

The service-centered viewed can be stated as follows:

1. Identify or develop core competences, the fundamental knowledge and skills

of an economic entity that represent potential competitive advantage.

2. Identify other entities (potential customers) that could benefit from these competences.

3. Cultivate relationships that involve the customers in developing customized, competitively compelling valve propositions to meet specific needs.

4. Gauge marketplace feedback by analyzing financial performance from exchange to learn how to improve the firm's offering to customers and improve firm performance.

Later on in their 2008 work, Vargo and Lusch (2008) made some modifications and additions to their original foundational premises (PFs'). (Table 2.1) They addressed that service is the fundamental basis of exchange, operant resources are the fundamental source of competitive advantage, and all economies are service economies. The customer is always a co-creator of value, and the enterprise cannot deliver valve, but only offer value propositions. A service-centered view is inherently customer-oriented and relational. All social and economic actors are resource integrators and value is always uniquely and phenomenologically determined by the beneficiary.

The last two PFs' add some NPO (non-profit organization) flavor to the service-dominant logic. And in addition, we are surprised to find out the similarity of value propositions between the shared decision making model from the medical society and the service dominant logic from the business world.

PFs	Modified/new foundational premise	Comment/explanation
PF1	Service is the fundamental basis of exchange.	The application of operant resources (knowledge and skills), "service," as defined in S-D logic, is the basis for all exchange. Service is exchanged for service.
PF2	Indirect exchange masks the fundamental basis of exchange.	Because service is provided through complex combinations of goods, money, and institutions, the service basis of exchange is not always apparent.
PF3	Goods are a distribution mechanism for service provision.	Goods (both durable and non-durable) derive their value through use – the service they provide.
PF4	Operant resources are the fundamental source of competitive advantage.	The comparative ability to cause desired change drives competition.
PF5	All economies are service Economies.	Service (singular) is only now becoming more apparent with increased specialization and Outsourcing.
PF6	The customer is always a co-creator of value.	Implies value creation is interactional.
PF7	The enterprise cannot deliver value, but only offer value propositions.	Enterprises can offer their applied resources for value creation and collaboratively (interactively) create value following acceptance of value propositions, but can not create and/or deliver value independently.
PF8	A service-centered view is inherently customer oriented and relational.	Because service is defined in terms of customer-determined benefit and co-created, it is inherently customer oriented and relational.
PF9	All social and economic actors are resource integrators.	Implies the context of value creation is networks of networks (resource integrators).
PF10	Value is always uniquely and phenomenologically determined by the beneficiary.	Value is idiosyncratic, experiential, contextual, and meaning laden.

Table 2.1 Service-dominant logic foundational premise modifications and additions (Vargo and Lusch 2008)

2.4 Innovation— the EVAR Experience and Design-Driven Innovation

2.4.1 History of Early Innovation and Development of EVAR

The first EVAR was performed by Parodi and associates using a Dacron graft sutured onto balloonexpandable Palmaz stents at the Instituto Cardiovascular de Buenos Aires (ICBA) on September 7, 1990 . (Parodi 1991) Since then, a number of commercially manufactured stent-graft devices have been developed and tested.

Much work, experimentation and design preceded the launch of the clinical program. Parodi (1997) wrote that he was a resident in vascular surgery at the Cleveland Clinic in 1976, where he learned a sad truth: in aged and very sick patients, the results of therapy—even the most advanced—were sometimes dismaying. To counter this, Parodi began to think of less traumatic ways to overcome the drawbacks of a major operation and dreamed of a day when patients with aneurysms could be treated under local anesthesia in the outpatient department. Taking advantage of the large arterial lumens found in most aortic aneurysm patients, he conceived the idea of introducing a polyester graft into the artery from a remote site under fluoroscopic guidance. When the target area was reached, the graft could be anchored and both ends sealed by means of a metal component, which wound replace suture.

The first two projects failed. Parodi met Julio Palmaz in Washington DC in 1988 and realized that his stent was the component He needed to achieve good anchoring and sealing of an endoluminal graft. After completing 62 canine experiments, they performed the first successful human case as mentioned earlier.

Criado (2010) listed the perceived critical milestones that made it possible for Parodi to develop an entirely new treatment solution for AAA patients and do so before anyone else.

1. First and foremost, it was Juan Parodi who provided the indispensable creativity, inventiveness, requisite focus, and perseverance to follow through (for

many years) until his dream was complete.

2. Much of the work and development took place in Argentina, mostly away from the then-prevailing power centers of medical technology. At the same time, the ability and rapidity of transitioning from concept to bench and then to animal experimentation and on to human application was undeniably helped by the less constraining regulatory environment.

3. Meeting Julio Palmaz in 1988 was groundbreaking: his stent turned out to be the ‘‘missing link’’ that completed Parodi’s concept.

4. Hector Barone, a most capable industrialist and inventor, who manufactured and/or procured some of the most important components of the Parodi-Palmaz system, supporting each and every procedure performed during the initial phase of their experience.

5. Meeting John Bergan (in Miami) in June of 1991 led to the prompt publication of the first English-language report before the end of that year and at a time when no one else was listening!

6. Treatment of the first AAA patient in the US (on November 23, 1992) was instrumental in assuring large-scale dissemination in this country and beyond and providing further ‘‘validation’’ to the procedure and its potential.

2.4.2 Future Perspective of Technological Innovation in EVAR

Endovascular devices have been designed by trial and error, with bench and animal testing followed by human clinical trials to determine whether the devices are safe and effective.

Despite remarkable advances over the past 15 years, there are persistent concerns regarding the long-term durability of endovascular devices. This may be due to deficiencies in device design, which has lagged behind other industries in adopting

computational methods that are now routinely used to design, develop, and test new aircraft and automobiles. Similar computational design and failure mode simulations that evaluate performance under stress conditions have not been widely applied in the development of endovascular devices.

Advances in medical imaging and computational modeling now allow simulation of physiological conditions in patient-specific 3-dimensional vascular models, which can provide a framework to design and test the next generation of endovascular devices. This modeling will allow the prospective design of devices that can withstand the force variations in the cardiovascular system that occur during bending, coughing, and varying degrees of exercise, as well as the extremes encountered during sudden impact in contact sports. Utilization of computational design methodology that takes into consideration the physiology of the cardiovascular system will improve future endovascular devices so that they are safer and more effective and durable. (Zarins & Taylor, 2009)

2.4.3 Technology Epiphany: the Interplay between Technology Push and Design-Driven Innovation

From the previous discussion we can all agree that scientifically speaking, EVAR is a breakthrough technological innovation. What else can we expect from EVAR?

Verganti (2008) specially emphasized product meanings. Market-pull innovation starts from the analysis of user needs and subsequently searches for the technologies and languages that can actually satisfy them. Technology-push innovation is the result of dynamics of technological research.

Analysis of design-intensive manufacturers such as Alessi, Artemide, and other leading Italian firms shows that their innovation process hardly starts from a close observation of user needs and requirements. Rather, they follow a different strategy

called design-driven innovation. This strategy aims at radically change the emotional and symbolic content of products (i.e., their meanings and languages) through a deep understanding of broader changes in society, culture, and technology. Rather than being pulled by user requirements, design-driven innovation is pushed by a firm's vision about possible new product meanings and languages that could diffuse in society. (Verganti 2008). Figur 2.6 highlighted the major areas of action of the three modes of innovation. The overlap between technology push and design-driven innovation in the upper left corner of Figure 2.6 highlights that breakthrough technological changes are often associated with radical changes in product meanings—in other words, shifts in technological paradigms are often coupled with shifts in sociocultural regimes.

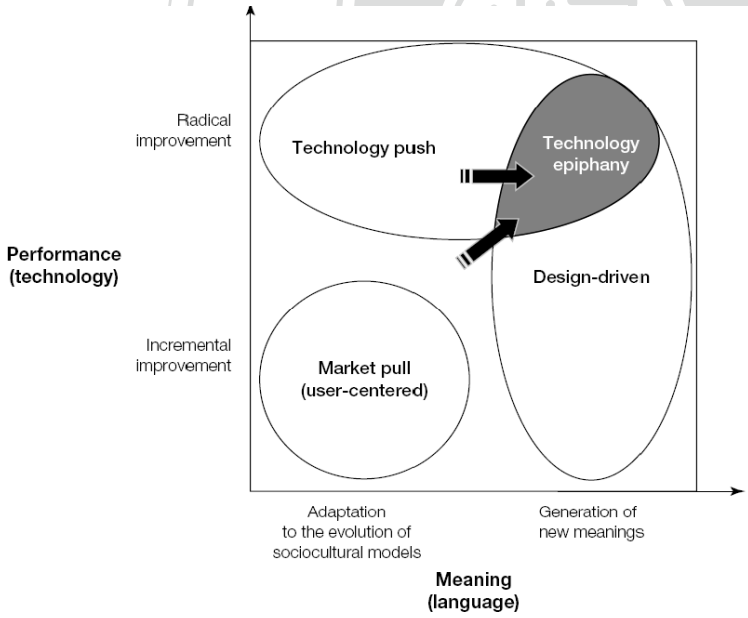

Figure 2.6 Innovation Strategies (Verganti, 2008)

Verganti proposed a metamodel for investigating design-driven innovation in which a manufacturer's ability to understand, anticipate, and influence emergence of new product meanings is built by relying on external interpreters (e.g., designers,

firms in other industries, suppliers, schools, artists, the media) that share its same problem: to understand the evolution of sociocultural models and to propose new visions and meanings. Managing design-driven innovation therefore implies managing the interaction with these interpreters to access, share, and internalize knowledge on product languages and to influence shifts in sociocultural models. (Fig. 2.7)

Figure 2.7 User-Centered Design and Design-Driven Innovation (Verganti, 2008)

2.5 Dissemination of Medical Innovation

2.5.1 History of Development of EVAR

The first EVAR was performed by Parodi and associates in 1991 using a Dacron graft sutured onto balloonexpandable Palmaz stents at the Instituto Cardiovascular de Buenos Aires (ICBA). (Parodi 1991) Since then, a number of commercially manufactured stent-graft devices have been developed and tested.

Six years after Parodi's initial work, Zarins and Harris (1997) commented in there review paper that in good-risk patients, aneurysms > 5 cm in diameter are best treated by replacement with a prosthetic graft. Operative mortality should be < 5% and 1-year survival > 90%. Aortic endograft techniques must meet or exceed these standards if they are to supplant standard surgical repair.

15 year after the first implantation, Rutherford (2006) summarized the three major trials, endovascular aneurysm repair (EVAR) 1 and 2 and Dutch Randomized Endovascular Aneurysm Management (DREAM) trials, and addressed that in patients with large AAAs who are fit for OR, EVAR offers an initial mortality advantage over OR, with a persistent reduction in AAA-related death at 4 years. However, EVAR offers no overall survival benefit, is more costly, and requires more interventions and indefinite surveillance with only a brief QOL benefit. It may or may not offer a mortality benefit over nonoperative management in patients with large AAAs who are unfit for open repair, but the statistical significance of this comparison is inconclusive.

Albuquerque et al. retrospectively analyzed non-suprarenal AAA repairs between January 1, 1996, and December 31, 2008, performed at a single institution. During a 13-year period, 721 patients underwent AAA repair, comprising 410 (56.9%) with EVAR and 311 (43.1%) with open repair. A bimodal distribution of EVAR usage was observed, with initial escalation in the 1990s to 70%. A nadir of EVAR occurred in the early 2000s (40%), correlating with more conservative EVAR use after the limitations of first-generation endografts were understood. Between 2005 and 2008, average EVAR use increased to 84%. Open AAA repair became more complex during the study period. The average rate for juxtarenal open AAA repair was 17.7% (range, 6.5%-34.6%) between 1996 and 2002 compared with 55.6% (range, 29.6%-100%) between 2003 and 2008 ($P < .05$). They concluded that AAA treatment has undergone a profound and sustained paradigm shift, now averaging 84% of repairs performed with EVAR between 2005 and 2008. Overall mortality from AAA repair, including ruptures, was reduced 64% (from 4.9% to 1.8%) during the 13-year study period. Although EVAR and open repair both had improved mortality in the latter half of the series, the primary driver in reduced mortality for AAA repair has been the shift to EVAR.

2.5.2 Adoption of EVAR

Without doubt, we've seen form the previous section that there has been a trend in adopting EVAR as the preferred treatment for AAA repair. Yet, priority setting in health care is a challenge because demand for services exceeds available resources. The increasing demand for less invasive surgical procedures by patients, health care institutions and industry, places added pressure on surgeons to acquire the appropriate skills to adopt innovative procedures.

Danjoux et al. conducted a qualitative case study (which is the only one the author could have found from the English literature on this issue on PubMed) of the decision to adopt EVAR using a modified thematic analysis of documents and semi-structured interviews in a Canadian medical center. Accountability for Reasonableness was used as a conceptual framework for fairness in priority setting processes in health care organizations. (Danjoux et al. 2007) Though this is the only work on the process of adoption of a new treatment modality, through their sophisticated review, the concept can be extrapolated to the majority of hospitals.

There were two key decisions regarding EVAR: the decision to adopt the new technology in the hospital and the decision to stop hospital funding.

They found that such innovations are often initiated and introduced by surgeons in the hospital setting. The decision to adopt EVAR was based on perceived improved patient outcomes, safety, and the surgeons' desire to innovate. This decision involved very few stakeholders. The decision to stop funding of EVAR involved all key players and was based on criteria apparent to all those involved, including cost, evidence and hospital priorities. Limited internal communications were made prior to adopting the technology. There was no formal means to appeal the decisions made.

2.6 Summary of Literature Review

2.6.1 Abdominal aortic aneurysm is a serious disease.

The most frequent site of extracranial arterial aneurysms is the infrarenal aorta and the natural history of AAAs is continuous expansion. Rupture is the most frequent and lethal complication of AAAs. The larger the aneurysm diameter is, the greater the risk for rupture is. Thus, the goal of elective AAA repair is to prevent rupture and prolong life. The 2003 Guidelines for the treatment of abdominal aortic aneurysms published by the Joint Council of the Vascular Societies noted that treatment of AAAs is individualized and recommended operative repair for AAAs with a diameter of 5.5 cm or greater in men. For women and patients with a greater than average rupture risk, an AAA diameter of 4.5 to 5.0 cm is an appropriate threshold for elective repair. For high-risk patients, delay in repair until larger diameter is warranted, especially if EVAR is not possible. The guidelines recommended EVAR as the most appropriate option for patients at increased risk with conventional open repair. It was emphasized that patient preference is of great importance.

2.6.2 Endovascular aortic repair is becoming the mainstream of AAA treatment.

The United Kingdom EVAR Trial Investigators published the trial result in New England Journal of Medicine in 2010. The 30-day operative mortality was 1.8% in the endovascular-repair group and 4.3% in the open-repair group. The endovascular repair group had an early benefit with respect to aneurysm-related mortality, but the benefit was lost by the end of the study. They concluded in this large, randomized trial, that endovascular repair of abdominal aortic aneurysm was associated with a significantly lower operative mortality than open surgical repair. However, no differences were seen in total mortality or aneurysm-related mortality in the long term. Endovascular repair was associated with increased rates of graft-related complications

and reinterventions and was more costly.

For high risk patients, they concluded that patients who were physically ineligible for open repair, endovascular repair of abdominal aortic aneurysm was associated with a significantly lower rate of aneurysm-related mortality than no repair. However, endovascular repair was not associated with a reduction in the rate of death from any cause. The rates of graft-related complications and reinterventions were higher with endovascular repair, and it was more costly.

2.6.3 EVAR is not as cost-effective as we expect.

Open repair is more likely to be cost-effective than EVAR on average in patients considered fit for open surgery. EVAR is likely to be more cost-effective than open repair for a subgroup of patients at higher risk of operative mortality. Evidence does not currently support EVAR for the treatment of ruptured aneurysms. Further follow-up of the existing trials should be undertaken and the relative costs of procedures and devices should be investigated further.

2.6.4 Patient participation should be encouraged and facilitated to co-create value.

Shared decision making is an approach where clinicians and patients communicate together using the best available evidence when faced with the task of making decisions, where patients are supported to deliberate about the possible attributes and consequences of options, to arrive at informed preferences in making a determination about the best action and which respects patient autonomy, where this is desired, ethical and legal.

Shared decision-making is increasingly advocated as an ideal model of treatment decision-making in the medical encounter. The particular decision-making context

that we focus on is potentially life threatening illnesses, where there are important decisions to be made at key points in the disease process, and several treatment options exist with different possible outcomes and substantial uncertainty.

Yet, not all patients want to participate to the same degree. In Levinson's study, nearly all respondents (96%) preferred to be offered choices and to be asked their opinions. In contrast, half of the respondents (52%) preferred to leave final decisions to their physicians and 44% preferred to rely on physicians for medical knowledge rather than seeking out information themselves.

Many patients neither appreciated the scope of their options before AAA repair nor felt adequately informed prior to making a decision. At the same time, the internet has the potential to provide patients with information and support as an adjunct to direct communication with the surgeon. Nevertheless, websites frequently accessed by patients often lack important information regarding surgical risk. Surgeons and other physicians who regularly discuss AAA management options with their patients should be aware of the potential for patients to arrive with preconceived notions based on what they have read online and be prepared to provide more complete information on risk and outcomes.

In the business encounter, Vargo and Lusch proposed a service-dominant logic and addressed that service is the fundamental basis of exchange, operant resources are the fundamental source of competitive advantage, and all economies are service economies. The customer is always a co-creator of value, and the enterprise cannot deliver valve, but only offer value propositions. A service-centered view is inherently customer-oriented and relational. All social and economic actors are resource integrators and value is always uniquely and phenomenologically determined by the beneficiary.

To our surprise, value propositions from different fields should ultimately join

together. That is, the shared decision making model is actually a service-dominant logic model.

2.6.5 EVAR Is a Technology Epiphany?

The first EVAR was performed by Parodi and associates in 1991 using a Dacron graft sutured onto balloonexpandable Palmaz stents at the Instituto Cardiovascular de Buenos Aires (ICBA). During the early development of EVAR technique and technology, first and foremost, it was Juan Parodi who provided the indispensable creativity, inventiveness, requisite focus, and perseverance to follow through for many years until his dream was complete. Meeting Julio Palmaz in 1988 was groundbreaking: his stent turned out to be the ‘‘missing link’’ that completed Parodi’s concept of anchoring a tube prosthesis to the neck of AAA endoluminally. Hector Barone, was a most capable, but least mentioned, industrialist and inventor, who manufactured and/or procured some of the most important components of the Parodi-Palmaz system, supporting each and every procedure performed during the initial phase of their experience. From these facts, we can conclude that EVAR technique and technology is a product of technology push— breakthrough technology innovation.

The very first possibility of dissemination of EVAR should be attributed to John Bergan who in 1991 led to the prompt publication of the first English-language report before the end of that year and at a time when no one else was listening. An important factor affecting the adoption of EVAR was that such innovations were often initiated and introduced by surgeons at the beginning in the hospital setting. The decision to adopt EVAR was based on perceived improved patient outcomes, safety, and the surgeons' desire to innovate. The decision to continue EVAR involved all key players and was based on criteria apparent to all those involved, including cost, evidence and

hospital priorities. In fact, EVAR had already gained wide acceptance before the recent availability of the clinical results of those large-scale trials. The reasons, though, were not thoroughly understood.

Chapter III

Research Methodology

This research is focused on the process of rapid adoption of an innovatively new endovascular aortic repair (EVAR) technique to treat abdominal aortic aneurysm within one year in a regional hospital in New Taipei City. At the same time span, the numbers of traditional open aortic repair procedures decreased rapidly. The author tried to answer the following questions:

What is the reason for this paradigm shift in the treatment of abdominal aortic aneurysm in this certain period of time?

Is the same reason specific only to this particular disease and its treatment or is it applicable to other medical arena as well?

3.1 Research Methodology

3.1.1 Research Design and Interview Guidelines

This is an exploratory and qualitative case study comprising 1) analysis of patient's medical records and hospital's financial records and 2) analysis of an in-depth interview.

The study started with a quick description of the hospital setting in which these operations were carried out. The process of introduction of the product into the operation room and incorporation of the implantation techniques into their daily practice was also prescribed.

Medical records of all those patients undergone either EVAR or open surgery were collected. A brief analysis of the medical records was provided. Each surgeon's pre-operative assessment and recommendation and each patient's pre-operative

informed consent were carefully read to figure out the reason why a given patient was assigned to a given procedure. Medical expense of each case was obtained from the administration section, and the medical expenses between the two groups were compared.

In-depth interviews with two surgeons working with the case hospital and seven industry persons were conducted. According to the literature review and the research framework, the researcher developed the following six questions as the interview guideline:

1. How many years have you been working as a surgeon or in the medical product industry? What is your field of specialty ?

2. How do you promote the EVAR-related products in the market? Do you need any knowledge or skill different from those you used to promote other products in the past? Is there any new business model?

3. Does EVAR have any influence on the behavior of medical product suppliers?

4. Does EVAR have any influence on the behavior of payers (in this aspect it means mainly the national health insurance system), medical service providers, or patients?

5. Whether EVAR (endovascular stentgraft) is a successful operation (product) and why?

6. Please describe the essential features of a successful operation (product).

The research finally used the combination of the analysis of the information from the medical records, the information from the in-depth interview, and the results and theories in the literature reviewed to generate the final conclusion and future perspective.

3.1.2 Information Collection

The interviewees were from both the medical service provider, that is the case

hospital, and the medical product supplier, that is the industry. One of the two senior cardiovascular surgeons who performed the majority of these cases in the studied hospital was interviewed. Another young vascular surgeon who joined the group recently was also interviewed. Seven business men from two major medical product supplier system in Taiwan were also interviewed. Table 3.1 listed the interviewees' position, location, and years in the field, and interview methods.

Interviewee	Specialty	Years in the field	Interview method
Dr. T, Chief surgeon	Cardiac and vascular surgery	22	Personal
Dr. H, Attending surgeon	Vascular and endovascular surgery	6	Personal
GM G, W. dealer company	Cardiac, vascular and anesthesia product	17	Phone and email
GM D, G. medical product company	General surgery, dental, and vascular product	20*	Phone and email
Technical Sales Specialist C, W. dealer company	Cardiac surgery and respiratory intensive care	8	Personal and email
Technical Sales Specialist L, G medical product company	Cardiology and endovascular surgery	6**	Personal and email
GM L, M. dealer company	Cardiac and vascular product	12	Personal
District Sales Manager S, M. medical product company	Cardiac surgery, endovascular and peripheral vascular surgery product	10	Personal
Technical Sales Specialist H, M. medical product company	Endovascular and peripheral vascular surgery product	7	Personal

Table 3.1 Interviewees' background and interview methods. *Mr. D had another 11 years' experience in orthopedic product, and **MR. L had been a senior sales representative in an international pharmaceutical company before he joined the present company. (source: the study)

Chapter IV

Case Description and Analysis

In this chapter, the author will first briefly describe the current features of the medical service in Taiwan as background information for readers not familiar with it. The process of the conduct, or the business model, of the new endovascular aortic repair and the traditional open surgical repair was then explained. This chapter will finally be focused on analysis and description of the reasons that the case hospital started to introduce the innovatively new surgical procedure and soon adopted the new procedure in almost every single patient, if not contraindicated.

4.1 Current Features of Medical Service in Taiwan

Concerning the overall provision of medical services in Taiwan, there has been a significant change after the commencement of the national health insurance system in March 1995. As the finance of national health insurance system continued to deteriorate, the National Health Insurance Bureau started the "global budget system" in July 2002 to control the increase of global medical expenditure. This resulted in the decrease of hospital revenue, yet increase in cost. In addition, competitors continued to join in the already saturated market. Efficiency and quality, which medical service providers emphasized the most in the past nowadays failed to overcome the changing environment. It has become a key issue for medical service providers to survive this environment of extremely limited resources with innovation in medical services.

Wang et al. (2005) cited Abernathy and Clark's (1985) innovation types and reported in their seminar paper that the majority of medical service providers now in Taiwan focus on regular innovation that can be easily imitated. They suggested that

medical service providers should aim at niche innovations, architectural innovations, and revolutionary innovations. (Fig. 4.1) Small-scale medical service providers are supposed to adopt the niche innovations strategy because of their insufficient resources. Those large-scale medical service providers with ample resources can adopt the architectural or revolutionary innovation strategy to offer new products or services to their existing customers or even to attract new customers.

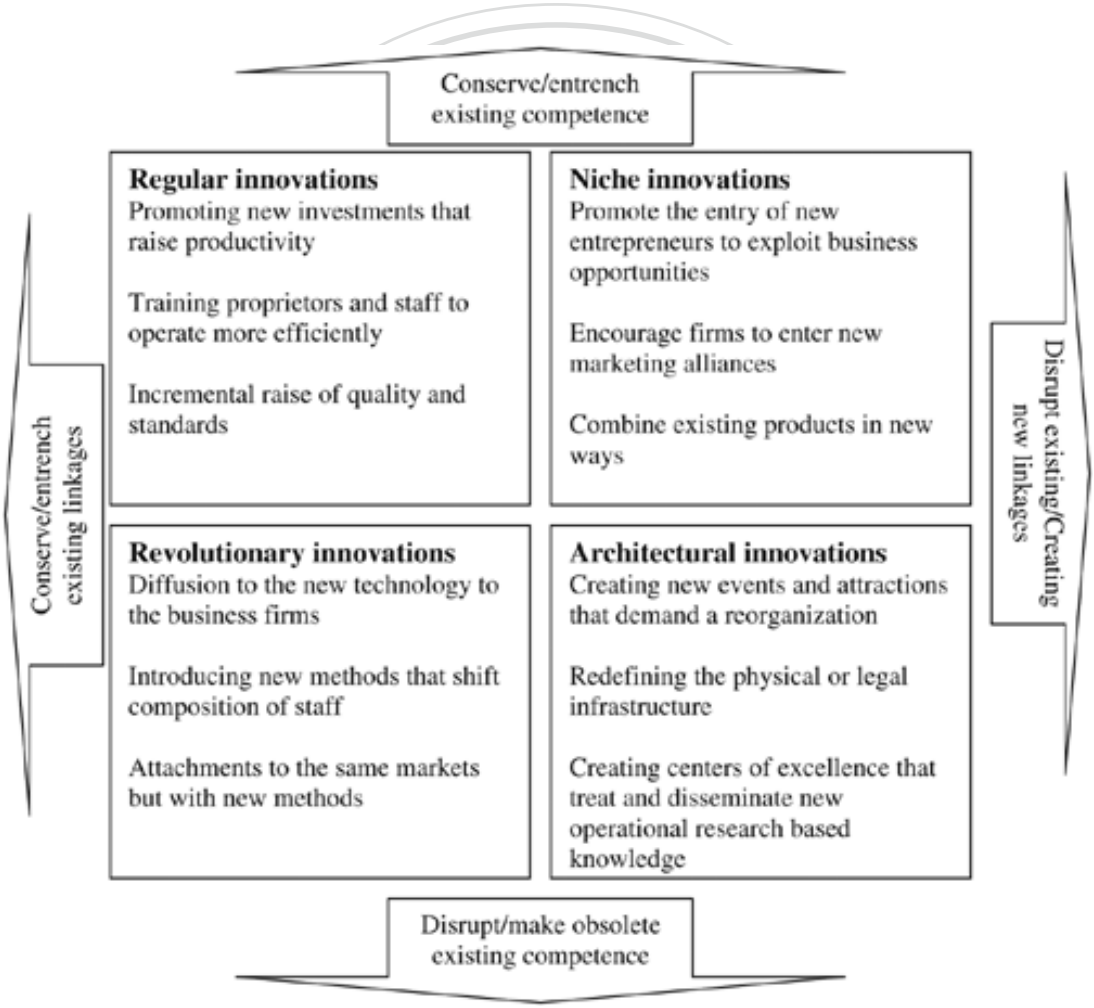

Figure 4.1 Abernathy and Clark (1985) Innovation types

4.2 Current Status and Strategy of the Case Hospital.

The case hospital is Buddhist Tzu Chi General Hospital, Taipei Branch. There

have been successively four cardiovascular surgeons. Currently two senior surgeons, amongst who the researcher is one, work with the hospital performing a large variety of major cardiac and vascular operations. A brief description of the case hospital as written by the superintendent Dr. You-Chen Chao is provided here.

"In the 1960s, life was extremely hard in Taiwan and people's living standard was low. Moreover, people who living in the east coast of Taiwan were very impoverished. Master Cheng Yen with great compassion responded to the suffering of the poverty-stricken and vowed to pour great love into the 'medical desert' of eastern Taiwan .In 1986, the first Tzu Chi General Hospital was established in Hualien. Yuli, Kuanshan, Dalin, Taipei and Taichung branches were opened accordingly. Tzu Chi medicine mission, just like the blossoming flowers of happiness and wisdom, spread from poverty-stricken east coast to the rest of Taiwan and formed a strong force of compassion that lives on endlessly.

Tzu Chi General Hospital, Taipei Branch was inaugurated on May 8, 2005. Under the collective support of Master Cheng Yen and global Tzu Chi volunteers, Tzu Chi built the first quakeproof hospital in Taiwan and well-known around the world. With the state-of-the-art, our hospital is designed to withstand the destructive forces of earthquake for thousand years. It is not only a new milestone for Tzu Chi medicine mission, but also a new ideal for humanistic medicine in the medical field of Taiwan. In the congested and chaotic medical environment, Tzu Chi General Hospital, Taipei Branch is an oasis of spirit brimming with tranquility, humanism and harmony.

Tzu Chi General Hospital, Taipei Branch is a large-scale hospital built to become the medical center filled with humanity. Besides of establishing the various medical specialties, exceptional fundamental, and state-of-the-art clinical services, we develop micro-invasive operations to minimize patients' suffering. In addition, it integrates with Tzu Chi massive network of community volunteers. With their great support, the

hospital promotes community health education as well as engages in health related and public hygiene work. The hospital also provides medical diagnosis, medical treatment, rehabilitation, and parent-children education for physically and mentally challenged children and their families.

Despite of the constant advanced medical technology that unravel the secrets of life, the innovation can only do so much to help the patients who still have to face the impermanence and unpredictability of life and the accompanying emotional suffering. In most of the situations, the patients need medicine treatment as well as spiritual comfort. Tzu Chi medical team comes together with the community volunteers to form a comprehensive team with the full of humanity. It highlights the spirit of empathetic love in "when others are hurt, we feel the pain; when others suffer, we feel the sorrow". More than 220 Tzu Chi volunteers serve at the Taipei Branch daily at various locations, no matter of rain or shine throughout the year. They communicate Tzu Chi great love to every patient and the families. This unceasing stream of selfless compassion flows through the whole hospital. Every year, over 70 thousand Tzu Chi volunteers become great resources for this medicine team and witness the precious life.

Life is priceless. Life and death are unexpected. Tzu Chi medical team always serves patients with humbleness and cherishes every second to safeguard life with vigilance. From doctors, nurses to volunteers, we devote ourselves to the mission of "guarding life, health, and love" with sincere "gratefulness, respect, and love."

Having weathered through many obstacles and challenges, Tzu Chi General Hospital, Taipei Branch stands firmly in the Taipei metropolitan landscape, brimmed with its humanistic spirit, first-rate medical team, and advanced medical technology. I anticipate every member of extraordinary team to embody our founder Master Cheng Yen's great compassion in carrying forth her dharma of relieving human

suffering, saving lives, and to sow the seeds of love in every community and around the world."

4.3 Endovascular Aortic Repair (EVAR) in the Case Hospital

4.3.1 Introduction of EVAR into the Department of Cardiovascular Surgery

The innovation strategy of our hospital is not only to establish various medical specialties, exceptional fundamental, and state-of-the-art clinical services, but also to develop micro-invasive operations to minimize patients' suffering. The department of cardiovascular surgery, following this strategy, has been providing both conventional major cardiac and vascular surgery and minimally invasive cardiac surgery including off-pump coronary artery bypass grafting (OPCAB), videoscopically-assisted cardiac operations (eg. EndoACAB, videoscopic mitral valve repair, and etc), and traditional cardiac operations though small wounds. Every effort had been exercised to make the organization an efficient and safe one. This is our regular innovation strategy.

As afore-mentioned in the first section of this chapter, for a 750-bedded regional hospital with sufficient resources and supporting system and located in the metropolitan area full of competition, we must consider periodic revolutionary innovation on top of continuous regular innovation to keep the hospital from stagnation. Though the two senior cardiovascular surgeons, amongst whom the author is one, were trained in the traditional ways in their residency and have been practicing accordingly for a long time, we agreed to this point of view and decided to embrace the chance to adopt a revolutionary surgical technique, that is EVAR, early in 2009. We simultaneously started our thoracic endovascular repair (TEVAR) program. While TEVAR shared many similar technical requirements with EVAR, it is not included in the study.

At the same period of time, in our daily practice, we treated patients with

abdominal aortic aneurysm larger than 5.0cm routinely with transperitoneal open abdominal aortic aneurysm resection and grafting, which had been the traditional and well-established treatment modality. As part of the innovation program, we had to prepare the whole surgical team for the necessary knowledge and surgical techniques through off-line lectures and on-line practice. The two surgeons attended several simulation courses and had been practicing peripheral vascular interventions to train themselves with the catheter techniques mandatory to the new procedure. An experienced endovascular surgeon was invited to supervise the first five cases.

Not only EVAR in comparison to the traditional open surgical repair (OSR) is an innovatively new procedure, but also the devices (endovascular stentgraft) to be implanted are much more complex and expensive than the vascular prosthesis used in the traditional open surgery. To cope with these challenges, a new business model between the industry and the medical service providers (including the case hospital) in Taiwan has been developed.

4.3.2 Conduct of EVAR in Regional Hospitals (including the case hospital) in Taiwan

For several decades, cardiac and vascular surgeons are trained and required to be familiar with both their surgical techniques and the characteristics of those medical devices to be implanted. In the hospital settings, a whole range of prosthesis or devices of different models and sizes should always be available on shelf for elective and emergent operations. During an operation, a surgeon can modify his/her surgical procedures upon observation of the particular anatomical variation and the actual model and size of the prosthesis most of the time is determined after assessment of the patient's anatomy during the operation.

In the daily practice of the open surgical repair, a patient sees a doctor for

surgical consultation and performance of the operation. The surgeon provides recommendation on choices of treatment and conducts the operation with his surgical team in the operation theater. After the operation, the surgeon also takes care of the patient in the ward and later in the out-patient department. Patients generally don't need to have further computed tomography angiography after open surgical repair unless specifically indicated in certain circumstances. The fee for medical services and expenditure on prosthesis are reimbursed separately by the insurance company (in Taiwan's case, the national health insurance system). The business model of the traditional surgery melieu is demonstrated in Fig. 4.2.

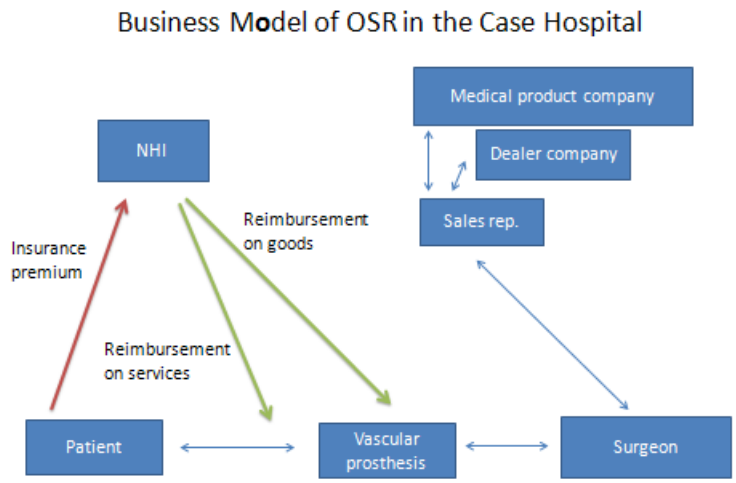

Figure 4.2 Business model of the traditional surgery melieu. (source: the study)

The service process of EVAR is slightly different from OSR. Before each operation, surgeons have to read the reconstructed computed tomography angiography (CTA) to make a surgical planning, comprising steps of procedures and the proposed choices of model, size and length of the endovascular stentgraft to be implanted. During the operation, the whole procedure is conducted under real-time fluoroscopy and angiography guidance. Postoperatively, patients are followed up closely on

out-patient basis and must undergo periodic computed tomography angiographies according to the institute policy and protocol. During each operation, the steps of procedures can vary because of anatomical and technical consideration and the actual model, size and length of the endovascular stentgraft to be implanted can also vary a lot. Traditionally the vascular prostheses are supplied on the shelf. This can be a problem for endovascular surgery considering the complexity and high price of the devices.

To conquer this situation, the industry and the medical service providers have developed a new business model. The industry has now a “technical sales specialist” who is well trained in the knowledge of endovascular surgery and very much familiar with its devices. While surgeons are performing the operation, the technical sales specialist will be in the operation room carrying ample supply of a wide range of models and sizes of the endovascular stentgraft and to offer detailed information on those devices to the operating surgeons. Instead of a sales specialist, he/she also serves as a technical specialist when it comes to the special features of the devices. The business model of the EVAR melieu is demonstrated in Fig. 4.3. Details of the development and operation of the business model will be prescribed further in the section of analysis of the in-depth interview.

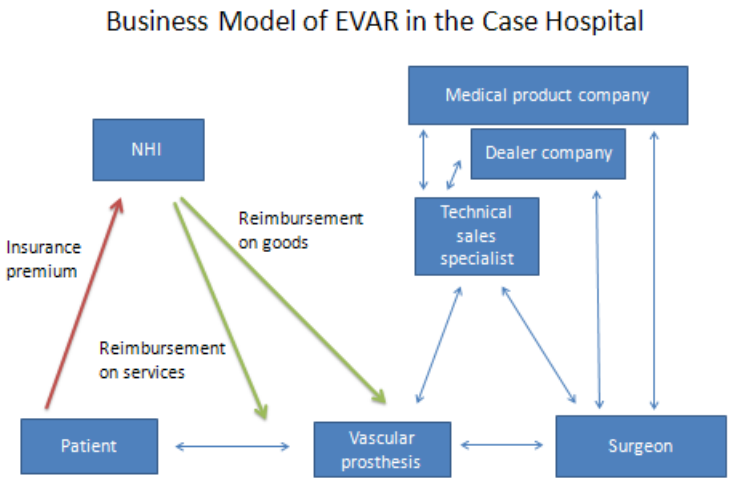

Figure 4.3 Business model of the EVAR melieu. (source: the study)

4.4 Paradigm shift in surgical treatment of abdominal aortic aneurysm

The endovascular stentgraft used in EVAR had not been reimbursed by the national health insurance system till February the 1st, 2010. Before that date, patients consented to EVAR had to pay an extra expenditure of approximately 500,000 NTD on the endovascular stentgraft. We started our EVAR program early in 2009, while only one out of the 6 patients with abdominal aortic aneurysm treated surgically in 2009 consented to EVAR. On the contrary, yet not surprisingly, the numbers of patients treated with EVAR soared in 2010 as the implementation of reimbursement. The numbers of patients treated with EVAR or OSR over these 6 years are demonstrated in Fig. 4.4.

From Fig. 4.4 we found that there was an evident paradigm shift in the modalities of surgical treatment of abdominal aortic aneurysm in our institute. Patients were treated solely with open surgical repair (OSR) from 2005 to 2009. From 2010 till now, most of our patients were treated with EVAR.

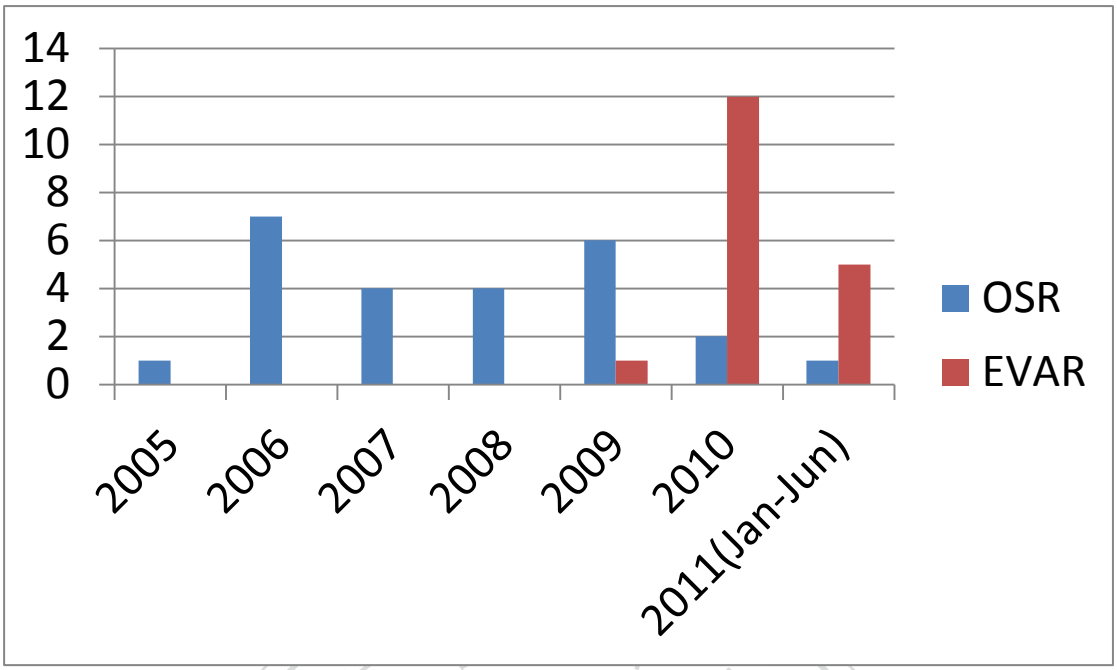

Figure 4.4 Numbers of EVAR and OSR (source: the study data)

When we looked at the patient data listed in Tab. 4.1, there was a definite male dominance (M/F = 42/1). Patients treated with open surgery (OSR) were slightly younger than patients treated with EVAR, though there was no statistical significance (73.3 vs 78.4, p=0.088). The length of hospital stay was significantly shorter in the EVAR group (10.9 vs 23.1, p=0.003). Nevertheless, the medical expenditure of the EVAR group is more than doubled that of the OSR group (633,146 vs 313,400, p<0.001).

	EVAR	OSR	p
Age (years)	78.4(55~93)	73.3(55~87)	0.088
Male/female	17/1	25/0	-
Length of stay (days)	10.9	23.1	0.003
Medical expenditure (NTD)	633,146	313,400	<0.001

Table 4.1 Patient data (source: the study data)

4.5 Analysis of In-depth Review

The previously mentioned questions were used as a guideline in interview. Three persons from W. dealer company and G. medical product company were interviewed through phone interview and written questionnaire. The others were interviewed in person.

The chief surgeon Dr. T, who has been working in the cardiac and vascular surgery profession for 22 years, responded and reported that he started performing minimally invasive cardiac surgery, mainly traditional operations through smaller wounds in the 1990's. He aborted these so-called minimally invasive operations later on when he thought that the invasiveness of these operations was not really reduced dramatically merely because of the smaller wound while there still being cardiopulmonary bypass. (author's note: The invasiveness and thus its possible adverse consequences of open heart surgery come mainly from median sternotomy and cardiopulmonary bypass.) Recently he concentrates on EVAR since he thinks that it is not just a modification of the traditional operation; on the other hand, it not only avoids the large laparotomy wounds, but also prevents the time of aortic clamping and thus a certain period of tissue ischemia. He believes that this is a true minimally invasive approach. However, the different surgical techniques and complexity of those devices did add difficulties in learning and adopting the new operation. Though the emergence of a technical sales specialist from the industry could compensate to a certain degree for the complexities, that is, the gap between the endovascular surgeon and the devices, he somewhat worried about the increasing importance of the role of the technical sales specialist. After all these successful operations and superb experiences, he stated that he could hardly recommend a patient to have open surgery again.

The young attending surgeon Dr. H was trained to be an endovascular surgeon in

his residency. He is competent in endovascular techniques and takes it for granted to first advising patients to have EVAR. He does not consider whether or not to do EVAR, but how to do it perfectly using state-of-the-art techniques and devices. Open surgery is not in his armamentaria unless endovascular surgery is not possible.

G. medical product company and M. medical product company are two of those major EVAR device suppliers in Taiwan. W. dealer company and M. dealer company are responsible for distribution of products.

The promotion strategies were different from before, said General Manager D from G. medical product company, who had 20 years' experience in marketing and distribution of surgical, dental and vascular surgical prosthesis and 11 years' experience in orthopedic surgery prosthesis. Mr. D reported that G. company's strategy was to promote the product in conjunction with its dealer and surgeons interested in this field. The G. company focused on branding and marketing. Experienced technical sales specialist from the G. company and the W. company offered expedite and comprehensive clinical technical support to surgeons both proactively and upon request. It was of equal importance both to offer official technical training courses to users, i.e. surgeons, and to offer them technical support in daily practice addressing the specific features of the product. In the EVAR business, the role of the industry and the dealer is no longer one who distributes and then collects money. In addition, they have become a specialist offering professional service to surgeons and patients.

Mr. L is the technical sales specialist under Mr. D. He had been a senior sales representative for an international pharmaceutical company for a couple of years. Also, he has been in the peripheral interventional field for 6 years. He responded that most of the time, he offers clinical technical support to surgeons in the operation theater, which is quite unique in the EVAR business. The industry has to be more professional,

and the interplay between NHI (National Health Insurance), hospitals, surgeons, and industry is more intimate and intricate than ever before.

General Manager G from W dealer company, which is the distributor of G's product, had been a businessman in the medical product field for 17 years. He reported that he used to focus on the characteristics of the product itself before. However, when dealing with EVAR product, salesperson, in addition to be familiar with the product, had to learn anatomy of the aorta, imaging technique, and surgical details of implantation.

Mr. C, technical sales specialist from W. dealer company, reported that when promoting EVAR product (endovascular stents), his first priority was to establish his professional image. When asked about whether this has any influence on his career, he responded that in this way, he could be valued higher by the society.

M. medical product company definitely had different strategy. It focused on the conduct of simulation training courses and development of image processing software, said district sales manager S. With this sophisticated image processing software, the company could make a delicate suggestion on surgical details and choices of devices upon surgeons' request. This will be of even greater value if surgeons' could not get detailed reconstructed computed tomography angiography form there in-house image department. M. medical product company emphasized on training courses and career development for surgeons. It tried to maintain a long-term relationship, said general manager L from M. dealer company.

Every interviewee agreed that EVAR is a successful surgical technique and endovascular stentgraft is a successful category of medical product. The reasons for its success, answered by interviewees, include minimal invasiveness, simple surgical techniques, less bleeding, low surgical morbidity and mortality, quicker recovery, shorter hospital stay, and improved quality of life. Durability of devices, improved

long-term survival and reasonable price were also mentioned by the industry persons.

4.6 Decision Making Process

Medical records of all patients were reviewed. Three stages of different decision making pattern could be identified.

EVAR was not available in our institute before 2009, and patients could only consent to open surgery. We started EVAR program in 2009, when EVAR was not reimbursed by the National Health Insurance System. From Jan 2009 to January 2010, eight patients were offered either EVAR or open surgery. We didn't know the exact reason, but only one out of the eight patients consented to EVAR. The 3rd stage started from February 1st, 2010, when EVAR get reimbursement. Except for two patients who were not good candidates for EVAR, we recommend EVAR to every patient; and these patients consented to EVAR.

Chapter V

Research findings

This study is focused on the process of rapid adoption of an innovatively new endovascular aortic repair (EVAR) technique to treat abdominal aortic aneurysm within one year in a 750-bedded regional hospital in New Taipei City. At the same time span, the numbers of traditional open aortic repair procedures decreased dramatically. The author tried to answer the following questions:

1. What is the reason for the paradigm shift in the treatment of abdominal aortic aneurysm in this certain period of time?
2. Is there a specific innovation model in the transformation process from traditional open surgery to modern less invasive surgery?

5.1 Reasons for Paradigm Shift

5.1.1 Newly Defined Meanings to Multiple Stakeholders Are the Reasons for Paradigm Shift in Clinical Medical Service — Patient Perspective

As previously mentioned, abdominal aortic aneurysm is a serious disease in the aged population and it carries high risks of morbidity and mortality once ruptured. Often being asymptomatic, yet after rupture of an AAA, only half of patients arrive at the hospital alive, and approximately half of them survive to discharge.

The goal of elective AAA repair is to prevent rupture and prolong life, at the tradeoff of an estimated mortality rate of elective open infrarenal AAA repair in good-risk patients of less than 5%. The operative mortality was 1.8% in the endovascular-repair (EVAR) group and 4.3% in the open-repair (OSR) group in EVAR-I trial. There was no significant difference between the two groups in the rate

of death from any cause and the rates of graft-related complications and reinterventions were 3- to 4-fold higher with endovascular repair, and new complications occurred up to 8 years after randomization, contributing to higher overall costs. Even though these inconclusive data, vascular surgeons worldwide have been witnessing a seemingly irreversible and accelerating trend towards EVAR. Why is there this discrepancy?

It is emphasized that patient preference is of great importance and it is essential that the patients be well informed to make such choices. Though logistically and statistically scientific enough, literatures on how a surgeon make decision on treatment plan and thus inform a patient, and how a patient feel as well as apprehend the recommendations, and finally achieve its decision in the real world have been scanty, if not lacking. As we can see from the author's review of the medical records, most patients consented to what they were recommended without even being informed of or asking for an alternative treatment. They tended to search information from paramedical literatures, online information, and opinions from personal social network. There is an atmosphere in these networks that EVAR is a safer procedure—interpretors' interpretation. This interpretation renders EVAR a generally accepted embedded meaning of being "a better treatment", thought anecdotal.

Figure 5.1A illustrates the technology-assisted service encounter in which the server delivers its services with the assistance of technology. The customer has no direct contact or utilization with the technology. Traditionally, medical service is a typical technology-assisted service encounter, consisting of two separate, however, closely inter-related communication systems: one between the industry and the physician, and the other one between the physician and the patient. The physician is of the pivot role that not only ensures the execution of treatment but also evaluates the results. Figure 5.2B illustrates the technology-assisted service encounter with

presence of interpretor. With multiple separate, yet closely related, communication systems, the different role in this service encounter can have vague but substantial influence on each other through its individual input and contribution to the "pool" of interpretation.

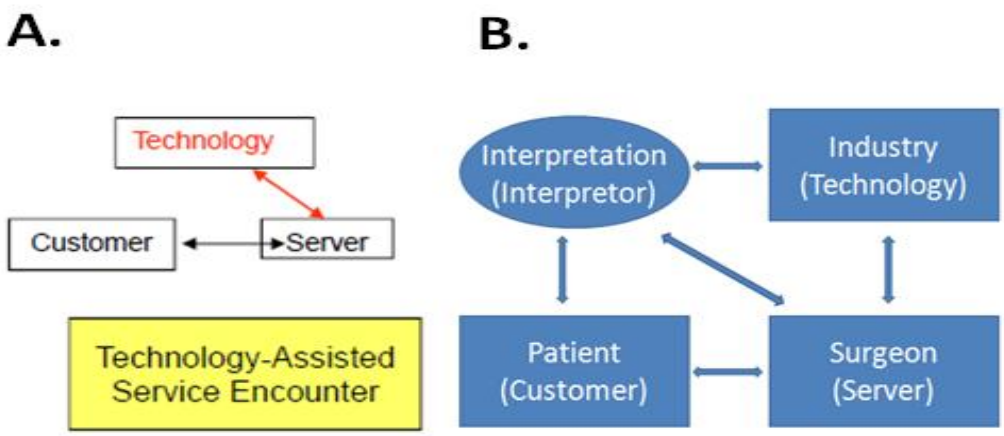

Figure 5.1

A. Technology-assisted service encounter.

B. Technology-assisted service encounter with the presence of interpretor.

(Source: the study)

5.1.2 Newly Defined Meanings to Multiple Stakeholders Are the Reasons for Paradigm Shift in Clinical Medical Service — Provider Perspective

No doubt the weight will certainly skew to the EVAR side when industry is considered. Revenue, of course, is the most obvious but not the only incentive and drive. Analysis of information from the in-depth interview showed that the majority of the industry persons feel much more satisfied with their professional role and work, in comparison to their previous job experiences. Through the industries' ability and possibility to convey influence on the interpretation of meanings of their products and

indirect yet vivid participation in the process of delivery of medical services to patients, the medical industry now has transformed itself into a partner of the medical service providing society.

Finally, we have to make an interpretation on surgeons' behavior. Two questions can be raised. First, why will a surgeon leave his/her comfort zone of well-established daily practice pattern to learn and adopt a new technique? Second, since to tell the even trivial difference in clinical results between different treatment modalities is an essentially integrated part of a surgeon's training and capability, then why should a surgeon prefer a treatment (EVAR) that is not evidently superior to the others (OSR or watchful waiting)? To answer these questions, we have to begin with exploring the unique characteristics of a professional service expert, in this situation, a vascular surgeon. The most prominent characteristic of people who are attracted to professions such as the law, medicine, public accounting, investment banking, advertising, and most types of consulting is that they are significantly overrepresented by the "high need for achievement" personality. (Delong, Gabarro, and Lees, 2007) People with a high need for achievement are motivated by many drivers, but at their core they are motivated to perform as well as possible. The most fundamental motivator is challenging work. The task challenge lies in solving complex problems and figuring out solutions to puzzling questions. This is their lifeblood. Secondly, the high-need--for-achievement personality is motivated by the opportunity to compete. Such people try to be the best at whatever they're striving to do. They are also motivated by being part of an effort that is striving to become the best or one of the best in the business, such as belonging to a group that is doing the most exciting deals in the industry or niche.

Apparently, EVAR is now one of the most cutting-edge techniques and technologies in the field of vascular surgery. Genius surgeons pioneered in the

specialty field, and talented surgeons that followed became an elite group of true experts. Practicing vascular surgeons then, of course, are keen to be amongst those ones keep up with the world. Every vascular surgeon knows clearly the benefits and drawbacks of this technique; nevertheless, everyone is pushing the limits, his/hers and patients', in addition to routine daily operations. More and more patients with AAA of difficult anatomy for EVAR are being treated with advanced endovascular techniques today. The reasons for this unrelenting pursuit to conquer the most extreme cases are a surgeon's internal cravings for ultimate excellence and the provision of the best treatment a patient could anticipate. Patients with their personal preference on EVAR, especially those who have information from their personal social network and online literatures, will further positively reinforce the trend. EVAR technique and endovascular stentgraft have nonetheless become the perfect tools to convey this value, or in other word, to fulfill everyone's dream. Here again, we can feel the overwhelming influence from the invisible yet ubiquitous interpretors.

5.2 Innovation Model in the Transformation Process from Traditional Open Surgery to Modern Less Invasive Surgery

As Wang suggested in their seminar paper that medical service providers should aim at niche innovations, architectural innovations, and revolutionary innovations to offer new products or services to their existing customers or even to attract new customers in Taiwan, it is of paramount importance for medical service providers to have a systematic algorithm to direct and monitor the steps and progress of innovation.

Many distinguished innovations came from incidental findings and mishaps in medical history, and these innovations would oftentimes result in a drastic decrease in mortality of some lethal diseases. However, high level of standards of modern biotechnological development has made innovation process much more sophisticated

and structural. It's not easy to further decrease an already very low mortality. Even though technological feasibility is ascertained, many social, economic, and psychological factors will influence its acceptance by the market, that is, the medical society, patients, and sometimes payers. From the previous section, we know that newly defined meanings are the reasons for paradigm shift in clinical medical service. Thus in dictating service innovation, we must focus on the interpretation of meanings as well as the ascertainment of technological feasibility and success.

Take the paradigm shift in treatment of abdominal aortic aneurysm as an example, figure 5.2 illustrates the complex relationships between multiple stakeholders in the business model of a clinical medical service. There are two major issues in this model.

As illustrated in figures 4.2 and 4.3, medical service providers get their revenue largely from medical services (i.e. operation) and prostheses (i.e. vascular prosthesis or stentgraft). This is typical good-dominant logic. In this manner, the majority of studies and discussions focused on methods and results of surgical treatment: open surgery vs. EVAR. No treatment, or in other words careful waiting, in certain occasions, has long been forgotten by surgeons. With service-dominant logic, the combination of recommendation on treatment modality and execution of the services, that is valve co-created by surgeons and patients, constitute the comprehensive service of treatment for abdominal aortic aneurysm. Medical service providers should be compensated for by provision of this comprehensive service.

The other issue is the introduction of the concept of "interpretor" into the business model. The pivot role of a surgeon in the provision of medical service is undeniable. However, the importance of other roles in the service system is increasing. As the widespread use of information and communication technologies and online information, the discrepancy of knowledge on a specific disease and its treatment

between professionals and laymen is being reduced. As a result, the interpretation from interpretors, that could be an arbitrary combination of any of those stakeholders has a substantial influence on the direction of development of the system and vice versa. This influence could be on technological, economical, or psychological aspect.

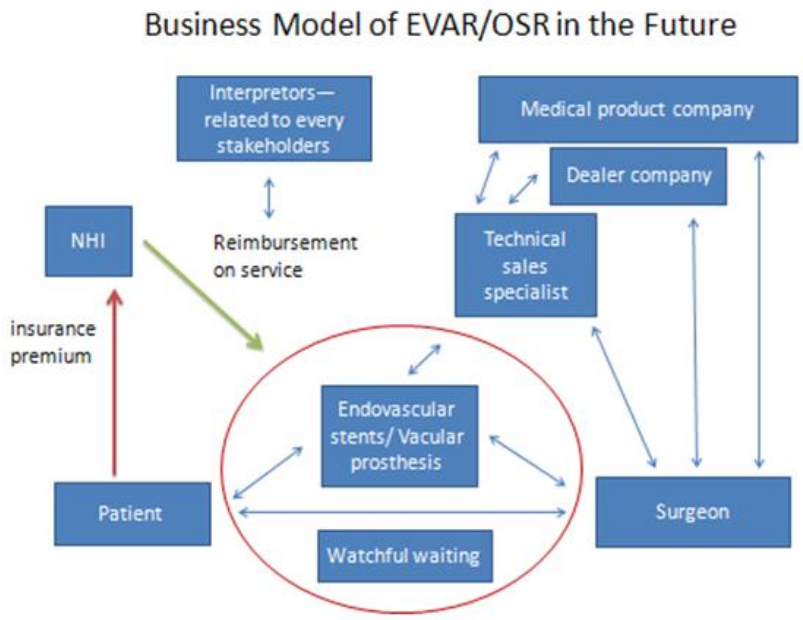

Figure 5.2 Business model of the combined SDL and Design-driven innovation milieu. Combination of recommendation on treatment modality and execution of the services in the red circle constitute the comprehensive service of treatment for abdominal aortic aneurysm. (source: the study)

Chapter VI

Conclusions and Future Perspectives

In modern surgical practice, what we consider as standard procedures today may be radical innovations dated back to the early days. Over the years, there have been frequent and constant modifications to the original surgical techniques, often incremental though. Most innovations in the field of cardiac and vascular surgery, or even in the overall medical industry, nevertheless didn't result in drastic changes in the standard daily practice. However, during the past several years, a paradigm shift in the treatment of abdominal aortic aneurysm (AAA) from open surgical repair (OSR) towards endovascular aortic repair (EVAR) was observed.

In comparison to the traditional open surgical repair, EVAR is associated with a significantly lower operative mortality and an early benefit with respect to aneurysm-related mortality. However, no difference is seen in total mortality or aneurysm-related mortality in the long-term, and EVAR is associated with increased rates of graft-related complications and reinterventions. In addition, EVAR is more costly. Even though, EVAR has become the mainstay of modern treatment of abdominal aortic aneurysm.

Traditionally, medical service is a typical technology-assisted service encounter, consisting of two separate, however, closely inter-related communication systems: one between the industry and the physician, and the other one between the physician and the patient. A physician (or surgeon) is of the pivot role that not only ensures the execution of treatment but also evaluates the clinical results in the technology-assisted medical service encounter. To encourage patient participation, shared decision making has been advocated; but in the real world situation, not all patients want to participate

in decision making. With the advancement of modern information and communication technologies, patients can easily search information from paramedical literatures, online information, and opinions from personal social network that can facilitate patients' ability to participate in decision making. This serves the emerging role of an interpretor. This interpretors' interpretation has substantial influences on, and can be reciprocally influenced by patients, surgeons, industry, and even payers. In this way, previously separated parts in the medical service system now can be joined together and closely inter-related. This is in concordance with the concept of co-creation of value in service-dominant logic.

From this study, it is concluded that newly defined meanings to multiple stakeholders are the reasons for paradigm shift in clinical medical service. To patients, it means the enhanced ability to participate in the decision-making process and thus to choose a seemingly safer and better treatment modality. To surgeons, it means not only to perform a state-of –the-art and cutting-edge procedure that can possibly offer a patient with the generally perceived and anticipated best available clinical results, but also to belong to an elite group of experts who play major roles in the special field. To a specific company in the industry, through the newly developed business model in which the company can contribute to the interpretation of meanings using the contemporary IC technology and provide comprehensive services on product information and implanting details by technical sales specialists, a specific company can establish its unique competition niche that could not be easily imitated.

Finally, the author cannot overemphasize the importance of introduction of the concept of service-dominant logic into the medical industry, both in daily practice and in innovation strategy. Multiple stakeholders are being involved much more than before in the process of co-creation of value in medical service. Future innovators must concentrate on meanings to multiple stakeholders as well on techniques and

technologies per se.

References:

1. 王嵩竑，徐純慧，謝錦堂「臺灣醫療產業創新策略之研究」，第三屆創新與創造力研討會論文，2005 年。
2. Albuquerque, F.C. Jr., Tonnessen, B.H., Noll, R.E. Jr., Cires, G., Kim, J.K., & Sternbergh, W.C. 3rd. (2010). Paradigm shifts in the treatment of abdominal aortic aneurysm: trends in 721 patients between 1996 and 2008. J Vasc Surg 2010;51:1348-52; discussion 1352-3.
3. Blackhouse, G., Hopkins, R., Bowen, J. M., De Rose, G., Novick, T., Tarride, J. E., & et al. (2009). A cost-effectiveness model comparing endovascular repair to open surgical repair of abdominal aortic aneurysms in Canada. Value Health 2009;12:245-52.
4. Brewster, D. C., Cronenwett, J. L., Hallett, J. W. Jr., Johnston, K. W., Krupski, W. C., & Matsumura, J. S. (2003). Guidelines for the treatment of abdominal aortic aneurysms. Report of a subcommittee of the Joint Council of the American Association for Vascular Surgery and Society for Vascular Surgery. J Vasc Surg 2003;37:1106-1117.
5. Chambers, D., Epstein, D., Walker, S., Fayter, D., Paton, F., Wright, K., & et al. (2009). Endovascular stents for abdominal aortic aneurysms: a systematic review and economic model. Health Technol Assess 2009;13:1-189, 215-318.
6. Chao, Y. C. “Words from the Superintendent.” available at: http://www.tzuchi.com.tw/tzuchi_en/About_TP_Center/Default.htm (retrieved June 13, 2011)
7. Charles, C., Gafni, A., & Whelan, T. (1997). "Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango)". Soc Sci Med 44 (5): 681–92.
8. Criado, F. J. (2010). EVAR at 20: the unfolding of a revolutionary new technique

that changed everything. J ENDOVASC THER 2010;17:789–796.

9. Danjoux, N. M., Martin, D. K., Lehoux, P. N., Harnish, J. L., Shaul, R. Z., Berstein, M., & et al. (2007). Adoption of an innovation to repair aortic aneurysms at a Canadian hospital: a qualitative case study and evaluation. BMC Health Services Research 2007, 7:182.
10. Delong, T. J., Gabarro, J. J., & Lees, R. J. (2007). "The High-Need-for-Achievement Personality. Motivating, Retaining, and Developing Your Talent." When Professionals Have to Lead. Harvard Business School Press 2007.
11. EVAR participants. (2005). Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): Randomised controlled trial. Lancet 365:2179-2186, 2005.
12. Gloviczki, P., & Ricotta, J. J. (2011). "Aneurysmal Vascular Disease:" Sabiston Textbook of Surgery, 18th Edition. Elsevier 2011.
13. Goldberg, C.G., Berman, L., & Gusberg, R.J. (2010). Limitations of online information on abdominal aortic aneurysm. Int J Vasc Med 2010;2010:789198.
14. Levinson, W., Kao, A., Kuby, A., & Thisted, R .A. (2005). Not all patients want to participate in decision making. a national study of public preferences. J Gen Intern Med 2005;20:531-5.
15. Moller, J.H., Shumway, S.J., & Gott, V.L. (2009). The first open-heart repairs using extracorporeal circulation by cross-circulation: a 53-year follow-up.Ann Thorac Surg. 2009;88:1044-6.
16. Parodi. J. C. (1997). Endoluminal treatment of arterial diseases using a stent-graft combination: reflections 20 years after the initial concept. J Endovasc Surg 1997;4:3-4.
17. Parodi, J. C., Palmaz, J. C., & Barone, H. D. (1991). Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991;5:491-499.
18. President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry (1998). "Quality First: Better Health Care for All

Americans". http://www.hcqualitycommission.gov/final.

19. Rutherford, R .B. (2006). Randomized EVAR trials and advent of level 1 evidence: a paradigm shift in management of large abdominal aortic aneurysms? Semin Vasc Surg. 2006;19:69-74.
20. Rutherford, R .B., & Krupski, W. C. (2004). Current status of open versus endovascular stent-graft repair of abdominal aortic aneurysm. J Vasc Surg 2004 ;39:1129-1139.
21. Salzburg Global Seminar. (2011). Salzburg statement on shared decision making. BMJ 2011;22;342.
22. Seelig, M. H., Oldenburg, W. A., Hakaim, A. G., Hallett, J. W., Chowla, A., Andrews, J. C., & et al. (1999). Endovascular repair of abdominal aortic aneurysms: where do we stand? Mayo Clin Proc 1999;74:999-1010.
23. Tarride, J. E., Blackhouse, G., De Rose, G., Novick, T., Bowen, J. M., Hopkins, R., & et al. (2008). Cost-effectiveness analysis of elective endovascular repair compared with open surgical repair of abdominal aortic aneurysms for patients at a high surgical risk: A 1-year patient-level analysis conducted in Ontario, Canada. J Vasc Surg 2008;48:779-87.
24. United Kingdom EVAR Trial Investigators, Greenhalgh, R. M., Brown, L. C., Powell, J. T., Thompson, S. G., Epstein, D., & Sculpher, M. J. (2010). Endovascular versus open repair of abdominal aortic aneurysm. N Engl J Med 2010;362:1863-71.
25. United Kingdom EVAR Trial Investigators, Greenhalgh, R. M., Brown, L. C., Powell, J. T., Thompson, S. G., Epstein, D., & Sculpher, M. J. (2010). Endovascular repair of aortic aneurysm in patients physically ineligible for open repair. N Engl J Med 2010;362:1872-80.
26. Vargo, S. L., & Lusch, R. F. (2004). Evolving to a new dominant logic for

marketing. Journal of Marketing, 68, 1–17.

27. Vargo, S. L., & Lusch, R. F. (2008). Service-dominant logic: continuing the evolution. J. of the Acad. Mark. Sci. (2008) 36:1–10.
28. Verganti, R. (2008). Design, meanings, and radical innovation: a metamodel and a research agenda. J PROD INNOV MANAG 2008;25:436–456.
29. Young, K. C., Awad, N. A., Johansson, M., Gillespie, D., Singh, M. J., & Illig, K. A. (2010). Cost-effectiveness of abdominal aortic aneurysm repair based on aneurysm size. J Vasc Surg 2010;51:27-32; discussion 32.
30. Zarins, C. K. & Harris E., J. (1997). Operative repair for aortic aneurysms: the gold standard. J Endovasc Surg 1997;4:232-241.
31. Zarins, C. K. & Taylor, C. A. (2009). Endovascular device design in the future: Transformation from trial and error to computational design. J Endovasc Ther 2009;16(Suppl I):I12–I21.