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H．知的財産権の出願・登録状況（予定を含む。）

1. 特許取得

特になし

2. 実用新案登録

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3.その他

特になし

厚生労働科学研究費補助金（医療安全・医療技術評価総合研究事業）
（分担）研究報告書

日本成人心臓血管外科手術データベース(JACVSD)におけるデータ収集のための Web-based データ入力システム開発に関する研究

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研究要旨

心臓外科手術領域はその高度な専門性と疾患特異性により、手術成績が直接生命予後を左右するという特色を持つ。このため一般消化器外科領域のごとく全国いずれの施設においても平均的な成績が得られるということはなく、施設間格差が生じているのが現状である。また、そのための診療技術評価法の検討も全国規模でなされたことはない。国民が知りたいのは各医療施設における診療技術の正しい評価、すなわち、自分が手術を受ける際にどの施設で受けるのがもっとも安全で高い治療効果が得られるかという点である。現時点でこれに答えられる情報は日本には皆無であり、全国的な情報収集システムの欠落がその主たる原因である。本研究では心臓外科手術患者をレジストリーというデータベース形式で把握するため、全国統一のフォームを用い、インターネットを用いてオンラインで情報を収集する。これに統計解析を加えた後その結果をインターネットを通じて医療施設だけでなく一般にも適正な形で開示しようとするものである。全国単位の成績はそのまま一般に開示されるが、各施設の成績はその施設にのみ出力される。施設がこれを一般に公開するか否かは各施設にゆだねられ、一部の優良施設は積極的に開示することが予想される。結果的に、全国レベルでの手術成績とともに各施設の成績という国民にとって最も知りたい情報がこの研究で得られるのである

A．研究目的

本邦における胸部外科関連の手術データベースを構築し、欧米アジア諸国とも共同して胸部外科手術のリスクを分析し、我が国における胸部外科手術の質の向上を計り、もって国民によりよい医療を提供するものである。

米国胸部外科学会データベースとほぼ同等の記入項目をインターネットを介して収集し、中央施設にて統計解析を行う。術前重症度に応じた手術危険率を計算し全国の施設にインターネットを通じて出力する。術前危険因子を欧米と統一しているので国内施設間はもとより欧米施設との直接

的な成績比較が可能となり、国内施設の成績向上につながる。　各施設でデータマネージャーを設置しその施設のデータ入力を責任を持って執り行うこととする。本研究では特に、このデータマネージャーに対してデータベース事業の目的を理解してもらい、正確で取りこぼしのないデータ入力を遂行してもらうために定期的に行うデータマネージャー会議推進を目的とする。

B．研究方法

インターネットを介したデータ記入システムを用いて既に全国主要施設で登録を開始している。参加施設の拡大を学会を通じて公募し、収集データを増大させる。また、質の高いデータを集めるためにデータの収集とvalidationを専門とする人員（データマネージャー）を育成し、正確な情報をインターネットを通じて収集・公表する。

1）データ入力フォームの作成：項目の選定はデータベースの質を決定する上で重要である。患者のID番号、生年月日といった一般的情報はもちろん、国名、病院名、執刀医名も記載する。術前に関連する因子として、合併疾患などの危険因子と患者の術前状態を入力する。手術手技、使用した医用材料、緊急度、補助手段、輸血の有無などは外科手術の中心をなす部分であり重要である。手術後の情報としては、死亡の有無、死亡原因はもちろんのこと、出血、感染、神経障害、臓器不全といった合併症を入力する。海外の成績と比較する上で海外の各データベースと統一性を保つため、アメリカのSTS National Database Data Collection Formおよびヨーロッパを中心としたInternational Adult Cardiac Surgery Data Collection Formの項目とほぼ一致するように配慮した。

（2）データ解析ソフト・ネットワークの開発：これまで日本胸部外科学会が行ってきた全国調査はアンケート形式であり、データ収集は年1回、郵送により収集されていた。術前危険因子に関する調査は無く、validationも不可能であった。本研究では全国大学病院医療情報ネットワーク(UMIN)との共同研究により、UMINをサーバーとし、インターネットを用いたデータ入力、validation、公表を行うこととした。これにより、データ収集の手間と経済性、正確性が大幅に改善される。

D．考察

各施設からの入力数はその施設で施行された手術の100%が入力されていることが理想であり、なおかつ正しい定義に基づいた入力や誤った使用方法を排除するといった点を積み重ねることによってクオリティーの高いデータベースが構築される。全ての施設で100%入力を達成しなければならず、今後はこの点に集中していきたい。そのためにもこのデータマネージャー会議を充実させることは極めて重要である。

E．結論

これまでの我々のデータからすると我が国の心臓血管外科手術成績は極めて良好で、欧米に全く引けをとらずむしろより良好であるともいえる。このデータを国内・国際的にも学術的な場面で公表し、日本の心臓外科手術領域の優秀性を広めていきたい。また、我が国の心臓外科手術の優秀性を広く一般国民にも理解していただきたく一般向けにも広報活動を進めていきたい。

F．健康危険情報

健康危険に関わる論点は本研究には属さないと思われる。

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H．知的財産権の出願・登録状況（予定を含む。）

1．特許取得

特になし

2．実用新案登録

特になし

3.その他

特になし

Japan adult cardiovascular surgery database: Second phase report for 2005-06.

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INTRODUCTION

The Japan Adult Cardiovascular Surgery Database (JACVSD) started in 2000 to estimate surgical outcomes following cardiovascular procedures in a multicenter basis in Japan. In May 2008 the database captures clinical information from 177 hospitals. The data collection form has 255 variables in total and these variables are almost identical to the STS National Database (available online at http://wts.org). The definition of JACVSD variables (available online at http://www.jacvsd.umin.jp) are the same as that of STS National Database. JACVSD constructed software for the web based data collection system, and through this system each data manager in the participating hospital is sending their data to the central office with his computer. While participation in the JACVSD is voluntary, data completeness is high. The accuracy of submitted data was maintained by checking through a data auditing, which some administrative office members visit a hospital randomly in monthly basis and check up data with clinical records. The validity of JACVSD data has further been confirmed in independent comparison of hospital cardiac surgery volume, entered to the JACVSD vs those reported to Japanese Association for Thoracic Surgery (JATS) Registry[1,2]. We included 85 centers in this report. These sites have been member of JACVSD from January 1, 2005 and entered enough data compared to those of JATS Registry.

ABSTRACT OF SURGERY

We examined all cardiovascular surgery procedures between January 1, 2005 and December 31, 2006. At first, records without patients' informed consent regarding JACVSD were excluded

from this analysis. Records with missing age (or out-of-range; under 18 or over 120), missing sex or missing 30 day status (n=1060) were also excluded. With the exception of body surface area, preoperative creatinine value and admission period, all missing or out-of-range values were imputed using the variable-specific median value. After this data cleaning, the population for this risk model analyses resulted in 21243 procedures from 85 participating sites throughout Japan. Based on JATS definition, 7083 procedures (33.3%) were classified into isolated CABG surgery, 6722 procedures (31.6%) were classified into valve surgery, 4651 procedures (21.9%) were classified into thoracic aortic surgery, and 2787 procedures (13.1%) were classified into others.

OUTCOME MEASURES

Primary outcome measure of JACVSD was 30-day mortality, defined as death within 30 days of operation regardless of the patient's geographic location. It includes death within 30 days of operation even when the patient has been discharged from the hospital. Second outcome measure of analysis was 30-day operative mortality, defined as in-hospital or 30-day mortality, and this is equivalent to the 30 day operative mortality which was expressed in the STS National Database. Major morbidity was as defined as any of 5 postoperative in-hospital complications: stroke, reoperation for any reason, need for mechanical ventilation for more than 24 hours following surgery, renal failure, or deep sternal wound infection[3]. In this analysis we use Composite operative mortality or major morbidity as the third endpoint.

RISK MODELS

Though isolated CABG surgery covers over 80% of all surgery in STS registration[4], isolated CABG surgery covers less than half of cardiovascular surgery in Japan. Therefore we develop risk model not only for isolated CABG surgery[5], but also for valve surgery[6] and thoracic aortic surgery[7]. We showed performance metrics for these models in Table 1. Except for 2 composite mortality or morbidity models all other risk models show good calibration and discrimination in 2005-06 records. The details of these risk models are also available in JACVSD websites (http://www.jacvsd.umin.jp/top.html). These models can be used to predict preoperative risk for each procedure and calculate risk-adjusted mortality ratios for each hospital. Risk-adjusted mortality rates for each hospital were calculated by dividing the observed outcome rate by the expected outcome rate at the hospital and multiplying by the overall outcome rate. Providing this information to doctors and other medical staffs can prove a stimulus to the introduction of a range of improvements in cardiovascular surgery, mainly with the aim of reducing avoidable deaths and morbidity[6].

ISOLATED CABG SURGERY

Distributions of Preoperative risks regarding isolated CABG surgery were shown in table 2.

Of these preoperative risks, "current smoking", "diabetes", "preoperative creatinine valve 1.5-3.0 or 3.0-", "cerebrovascular disease", "COPD (chronic obstructive pulmonary disease)", "extracardiac vascular disease", "congestive heart failure", "angina", "shock", "arrythmia", "NYHA class IV", "LV function bad", "aortic stenosis" , "reoperation" and "status (urgent, emergent, salvage)" were included in risk models of CABG surgery. We also show distributions of procedures regarding isolated CABG surgery in table 3. Of all 7083 procedures, 40.1% used cardiopulmonary bypass, and 16.8% use autologous blood. Table 4 indicates outcomes of isolated CABG surgery. An O/E Ratio can be calculated for any of the risk-adjusted outcomes for the allowable procedures. The O/E ratio is calculated by dividing the number of observed events by the 'expected' number of events in this study. The number of observed events is the number of procedure for which the event occurred. The number of 'expected' events is calculated using the appropriate risk-adjustment model. Based on JACVSD risk models 30-day mortality and 30-day operative mortality of 2006 were improving as compared with those of 2005. On the other hand, composite mortality and morbidity of 2006 was not improving as compared with those of 2005. Risk profiles of isolated CABG surgery during 2005-06 are shown in table 5. These results suggest there is little change in preoperative risk of each outcome (30-day mortality, 30-day operative mortality, composite mortality and morbidity) regarding isolated CABG surgery between 2005 and 2006. We also

present distributions of preoperative medication regarding isolated CABG surgery in Table 6. As for the preoperative beta-blocker use for isolated CABG surgery, the estimated usage rates of JACVSD (36.8%) were different from those of STS National Database (Median:72.8%)[7]. In addition to preoperative Beta Blockers usage, STS and National Quality Forum recommend discharge Antiplatelets usage, discharge Antilipids usage and discharge beta blockersusage as process measures[8]. In Japan more notice might need to be taken on discharge medication.

VALVE SURGERY

Distributions of Preoperative risks regarding valve surgery were shown in table 7. Of these preoperative risks, "Body surface area", "diabetes", "renal failure", "cerebrovascular disease", "infectious endocarditis type active", "COPD (chronic obstructive pulmonary disease)", "extracardiac vascular disease", "congestive heart failure", "angina", "shock", "NYHA class IV", "LV function bad", "Tricuspid insufficiency IV", "reoperation" and "status (urgent, emergent, salvage)" were included in risk models of valve surgery. We also show distributions of procedures regarding valve surgery in table 8. Of all 6722 procedures, 14.7% were combined with CABG surgery, 51.1% were aortic valve replacement, 26.4% were mitral valve replacement, 24.5% were mitral valve repair and 16.8% were tricuspid valve repair. Table 9 indicates outcomes of valve surgery. Based on JACVSD risk models 30-day mortality and

composite mortality and morbidity were improving as compared with those of 2005. On the other hand, 30-day operative mortality of 2006 was not improving as compared with those of 2005. As new AATS (American Association for Thoracic Surgery), STS and EACTS (European Association for Cardio-Thoracic Surgery) guideline for reporting mortality and morbidity after cardiac valve interventions[9] indicates that mortality is to be reported as all-cause mortality not only at 30-days, but also 60 or 90 days, JACVSD might well to follow up medium- to long-term outcomes.

Risk profiles of valve surgery during 2005-06 are shown in table 10. These results suggest there is little change in preoperative risk of each outcome (30-day mortality, 30-day operative mortality, composite mortality and morbidity) regarding valve surgery between 2005 and 2006. We also present distributions of preoperative medication regarding valve surgery in Table 11.

THORACIC AORTIC SURGERY

Distributions of Preoperative risks regarding isolated CABG surgery were shown in table 12. Of these preoperative risks, "history of smoking", "diabetes", "diabetes treatment" , "preoperative creatinine valve 2.0-4.0 or 4.0-", "COPD (chronic obstructive pulmonary disease)", "neurologic disfunction", "marfan syndrome", "aortic stent graft", "piror myocardial infarction", "history of cardiopulmonary resuscitation", "NYHA class IV", "LV function bad",

"reoperation" and "status (urgent, emergent, salvage)" were included in risk models of CABG surgery. We also show distributions of procedures regarding isolated CABG surgery in table 3. Of all 4651 procedures, 8.6% were combined with CABG surgery, 19.5% were combined with valve surgery, 43.5% were aneurysm type 'dissection' and 9.1% were aneurysm ope indication 'rupture'. As for range of replacement, 49.9% were 'ascending', 40.6% were 'arch', 19.7% were 'descending', 17.5% were 'distal aorta', 11.0% were 'root', 7.2% were 'thoracoabdominal', 0.9% were 'abdominal'. Of 4651 procedures, 2931(63.0%) used CNS protection; antegrade 1833(39.4%), retrograde 636 (13.7%), deep hypothemic or others 388 (8.3%). Table 14 indicates outcomes of thoracic aortic surgery during 2005-06. Based on JACVSD risk models all risk-adjusted outcomes (30-day mortality, 30-day operative mortality, composite mortality or morbidity) of 2006 were improving as compared with those of 2005.

In this study we selected 5 postoperative in-hospital complications (stroke, reoperation for any reason, need for mechanical ventilation for more than 24 hours following surgery, renal failure, or deep sternal wound infection) which former study proposed[3]. As these complications mainly targeted CABG surgery and Valve surgery, definition of complications might not be suitable for thoracic aortic surgery. In particular, rate of "need for mechanical ventilation for more than 24 hours following surgery" were too high (19.2%). Definition of prolonged ventilation regarding

thoracic aortic surgery might well change into "need for mechanical ventilation more than 72 hours following surgery". We also present distribution of "paraparesis" as complication of thoracic aortic surgery.

Risk profiles of thoracic aortic surgery during 2005-06 are shown in table 15. These results suggest preoperative risk of each outcome (30-day mortality, 30-day operative mortality, composite mortality and morbidity) regarding thoracic aortic surgery in 2006 decreased as compared with those in 2005. We present distributions of preoperative medication regarding thoracic aortic surgery in Table 16.

DATA FEEDBACK

As for quality improvement of cardiovascular surgery in Japan, it is very important to support each participant hospital identify their problem and improve their quality. The report form Cochrane Database of Systematic Reviews suggested that providing healthcare professionals with data about their performance (audit and feedback) may help improve their practice[6]. Because preoperative risk of each surgeries varies greatly in cardiovascular surgery, using only raw outcome rates for benchmarking were of limited use. JCVSD made annual benchmark report and provided them to each participant hospital. In this report, each hospital could

recognize their risk-adjusted outcome rates and preoperative risks compared with nationwide trend. Each hospital could also check up time trend of their risk-adjusted outcome rates and preoperative risks through web-based program.

These benchmark reports and programs were part of healthcare professionals' collaboration project for quality improvement of cardiovascular surgery in Japan. Birkmeyer[10] proposed two other methods (Pubic reporting, Pay for performance) for quality improvement of healthcare. However professionals' voluntary efforts to improve quality were most important for long-term outcomes and maintain improvement. We thought that to support hospital quality improvement through data feedback might be essential for all three strategies.

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Disclosures

None

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大学, 2004 年 7 月 14 日 site visit report

2004/07/15

大学心臓血管外科　克彦先生

site visit　参加者：本村昇、岡田 昌史、木下節子

結果概要:

総入力症例数 358 例 うち手術後 30 日後生存 339 例

生存症例入力率 100% 死亡症例入力率 100%

個別症例について:

管理番号: E0002061

手術日：2002/9/3

病院 ID：44-4936-8

氏名：NC

術後 30 日 dead

- 手術の procedure に入力がないので、「他の心臓手術」にチェックを入れる必要があります。
- Range of replacement が入力されていないので、入力の必要があります。

管理番号: E0001714

手術日：2002/10/7

病院 ID：46-3263-6

氏名：YS

術後 30 日 dead

- MAP：バルブにチェックがされていませんが、入力プログラムのミスでチェックが不可能になっているようです。
- 術後 PCPS のチェック漏れがあると思われます。

管理番号: E0005394

手術日：2003/7/11

病院 ID：35-2751-9

氏名：OS

術後 30 日 alive; 退院時 dead(術後 2 ヶ月)

- 術前 ECA が No となっていますが、Yes と思われます。
- 手術日が院内記録では 7 月 14 日となっているが　JACVSD では 11 日。

全体に関して:

1) Aorta に関連する項目が、現状では pre-operative risk section の extracardiac arteriopathy と、operation section の Other non-cardiac surgery しかありませんので、Aortic surgery に関しては細かなリスク要因がデータベースのデータから見えてこない可能性が示唆されました。今後入力項目の改訂時に項目追加を行いたいと考えております。
2) 2 回手術しているが、1 症例のみの入力となっている例がありました。JACVSD は procedure レベルの評価ですので、複数回手術例は基本的には複数症例として入力をお願いいたします。また、2 症例として入力される際には、同一患者でも pre-operative risk factor の値は異なってくるはずですので、risk factor を同一の値としないようご注意ください。
3) 術前から透析を行っている症例など、手術後 30 日で生存となっているが、死亡の転帰となった症例がみられ、Hospital mortality と 30-day mortality を併用することの重要性が示唆されました。
4) 現行の入力システムの使いにくさに起因する入力ミスが散見されました。CABG/Valve/Other cardiac/Other non-cardiac すべてが未チェックでも入力完了とできてしまうことや、Subcategory にチェックが入っていてもそのカテゴリーの詳細情報入力欄が自動的に有効にならない点などが入力ミスを誘発しているので、新ソフトウェアの実運用時に改善いたします。

ご協力ありがとうございました。今後ともよろしくお願い申し上げます。

2006/06/20 JACVSD

第 2 回 Site Visit 報告書

訪問施設： （2005 年 完了・ A ・ B （C））

日時： 平成 18 年 6 月 14 日 午前 9 時～午後 5 時 30 分

訪問者： 本村昇，岡田昌史，川原ユカリ，月原弘之 （敬称略）

訪問部署： 心臓血管外科 医局

TEL 075-251-5752

所属部責任者：

データマネージャー： 先生

入力担当者： 美映 様