目的

- DPC各臓器別にみた循環器の位置付け
- 循環器21疾患における心不全の位置付け

を

- 費用構造の特徴
- 収支差

から評価し、

- DPC制度下での適切な値決めを考えたい。

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方法: 原価計算を通じた医療費の分析

- 2病院を対象に原価計算を実施
  - 2007年4～6月入退院症例
  - A病院(民間病院 近畿地方 約500床)
  - B病院(公的病院 九州地方 約400床)

- 機能別原価計算(今中方式)
  - タイムスタディが基本
  - 共通費(含人件費)は賦課割合を現場と相談
  - DPCデータを活用し、患者別の資源利用に応じた配賦

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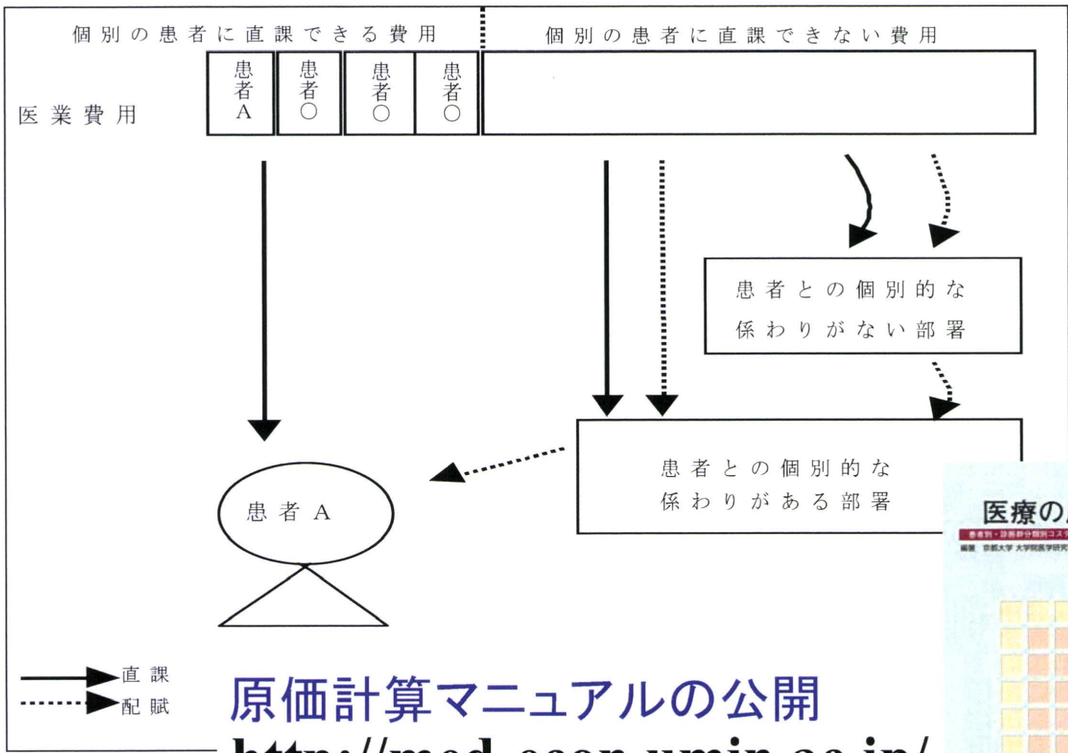
患者別原価計算の枠組み



原価計算マニュアルの公開

http://med-econ.umin.ac.jp/

『医療の原価計算』(社会保険研究所, 2003)

費目の詳細

給与費
- 給与費>医師・歯科医師>経験年数20年以上
- 給与費>医師・歯科医師>経験年数10年以上
- 給与費>医師・歯科医師>経験年数10年未満
- 給与費>医師・歯科医師>研修医
- 給与費>看護職員>看護職員
- 給与費>看護補助職員>看護補助職員
- 給与費>薬剤師>薬剤師
- 給与費>検査技師>検査技師
- 給与費>放射線技師>放射線技師
- 給与費>栄養士>栄養士
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- 給与費>その他医療技術員>その他医療技術員
- 給与費>診療情報管理士>診療情報管理士
- 給与費>ソーシャルワーカー>ソーシャルワーカー
- 給与費>事務員>事務員
- 給与費>技能労務員・労務員>技能労務員・労務員

材料費
- 材料費>医薬品費>投薬・注射(直課分)
- 材料費>医薬品費>投薬・注射(非直課分)
- 材料費>医薬品費>検査薬・その他
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経費
- 経費>賃借料>医療用器械備品賃借料(高額分)
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- 経費>賃借料>建物土地等賃借料(高額分)
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- 経費>雑費>雑費
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委託費
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- 委託費>清掃委託費>清掃委託費
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研究研修費
- 研究研修費>研究材料費>研究材料費
- 研究研修費>謝金>謝金
- 研究研修費>図書費>図書費
- 研究研修費>旅費交通費>旅費交通費
- 研究研修費>研究雑費>研究雑費

減価償却費
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- 減価償却費>医療用器械備品減価償却費>医療用器械備品減価償却費(その他)
- 減価償却費>その他減価償却費>情報システム減価償却費(高額分)
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役員報酬
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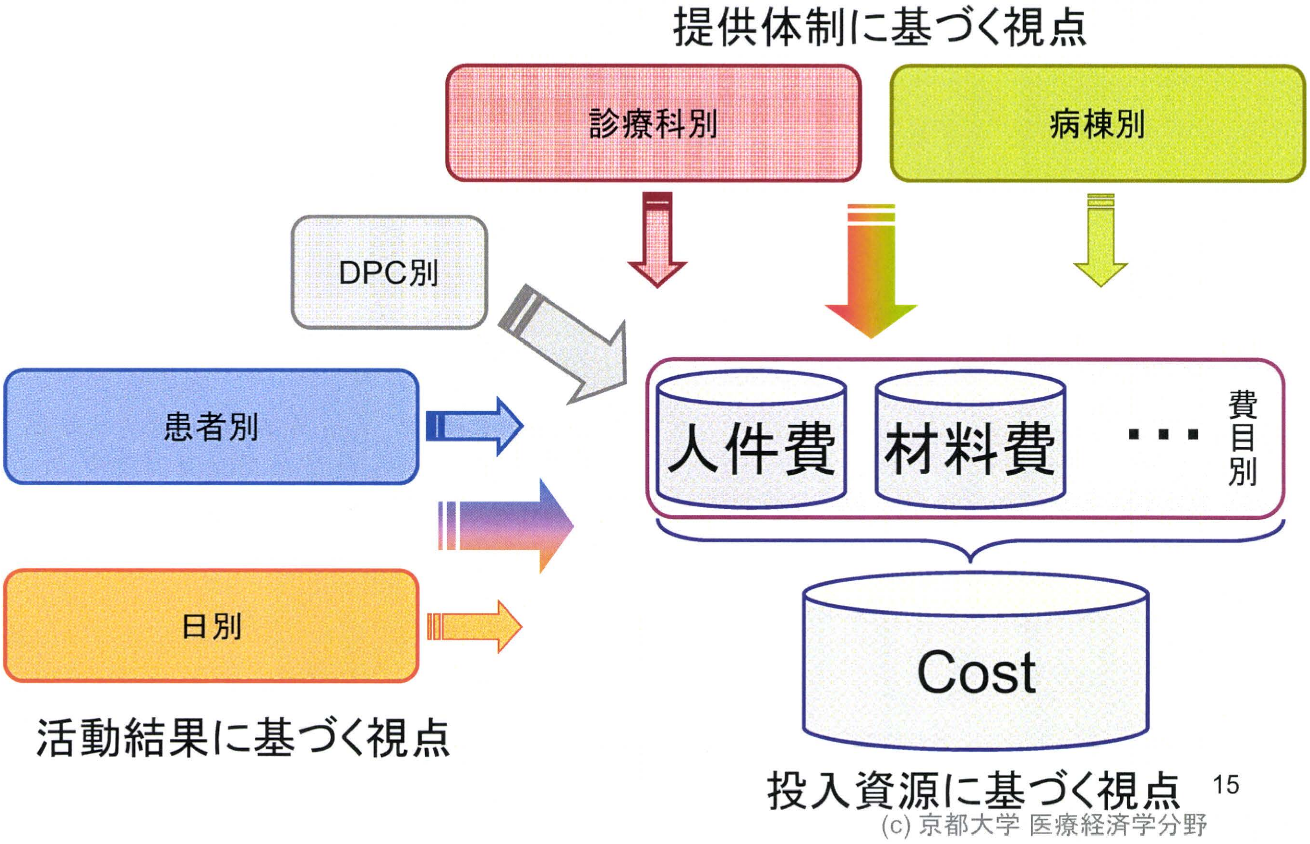
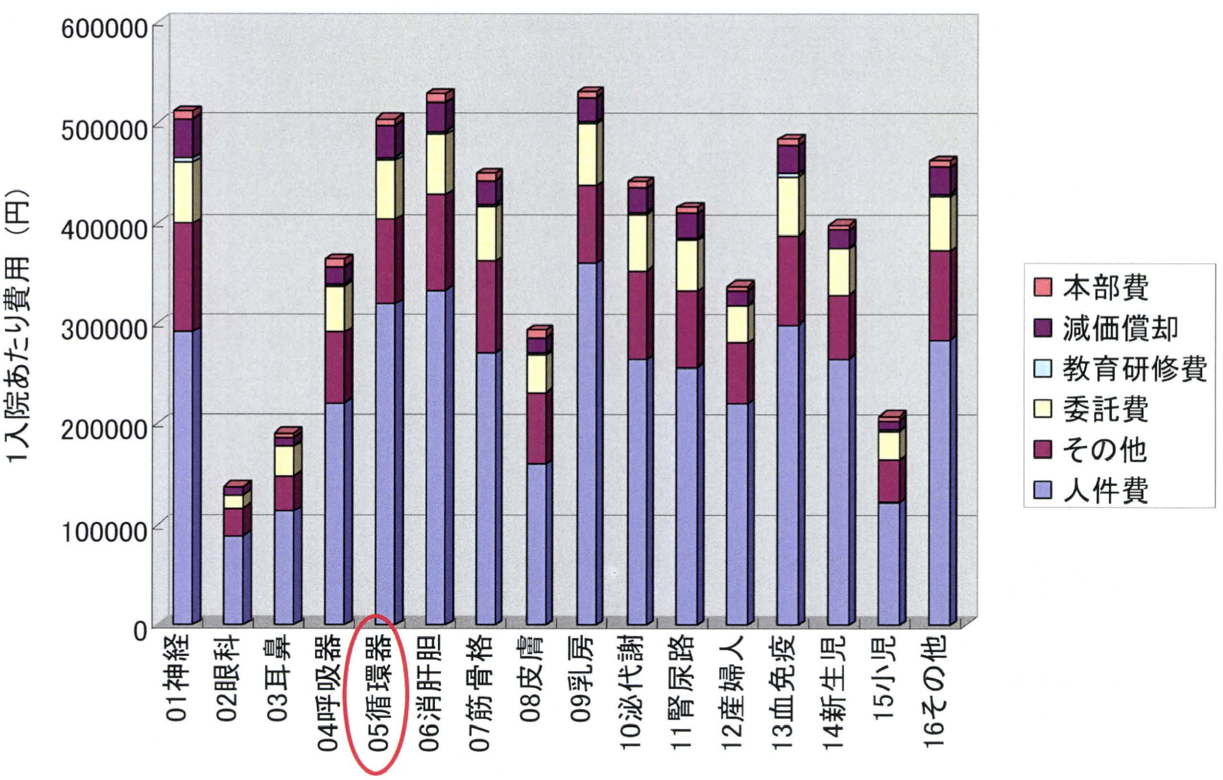
Cost 分析における視点の例



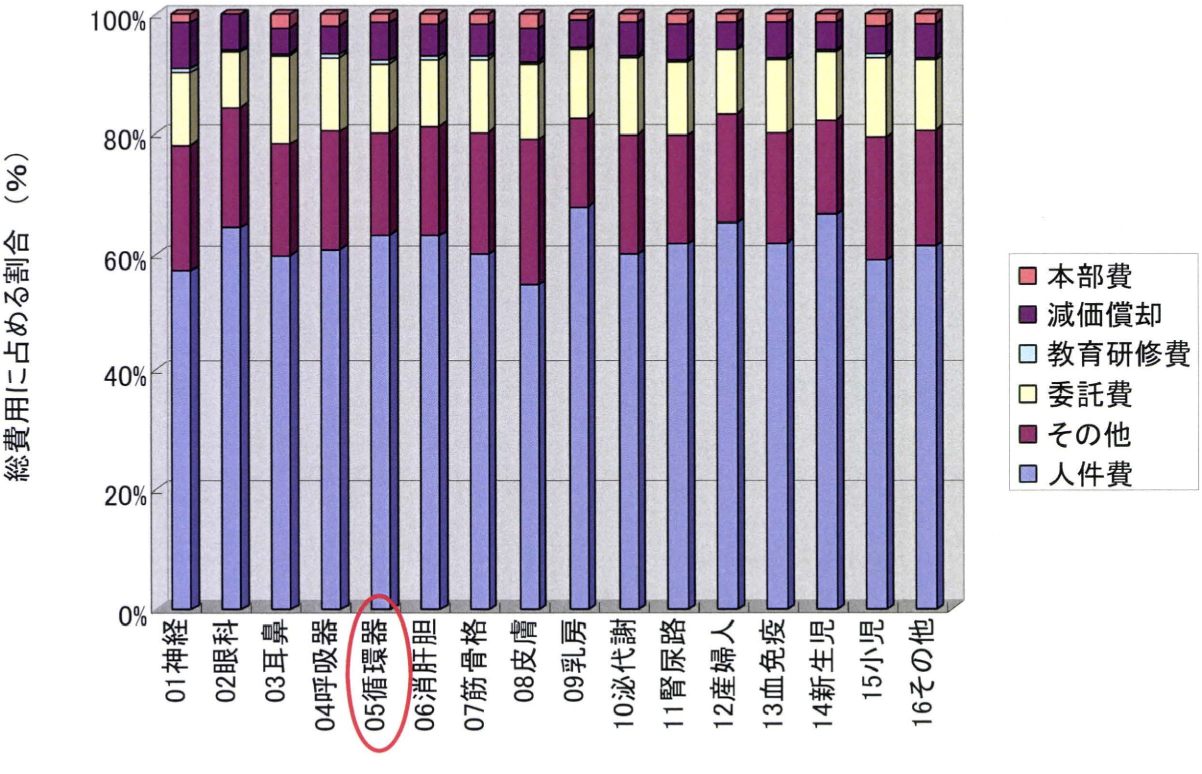
循環器診療の特徴

臓器別の原価



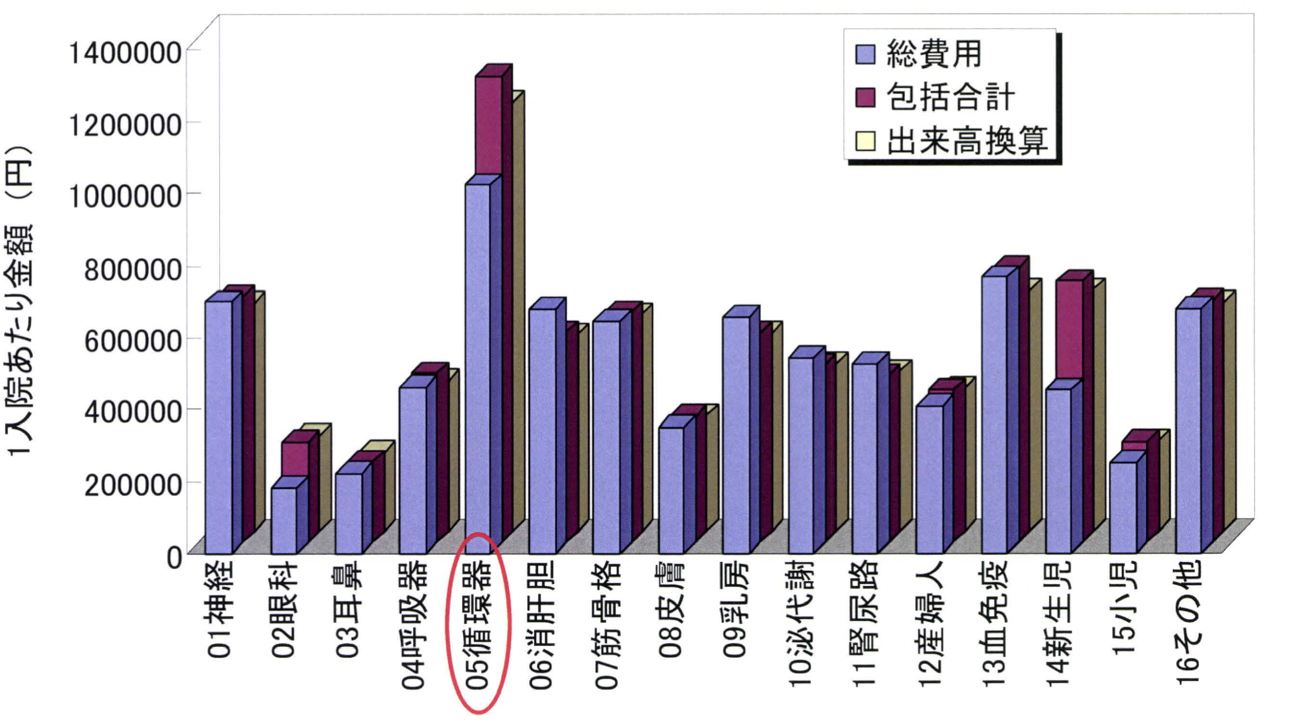
循環器診療の特徴

臓器別の費目割合

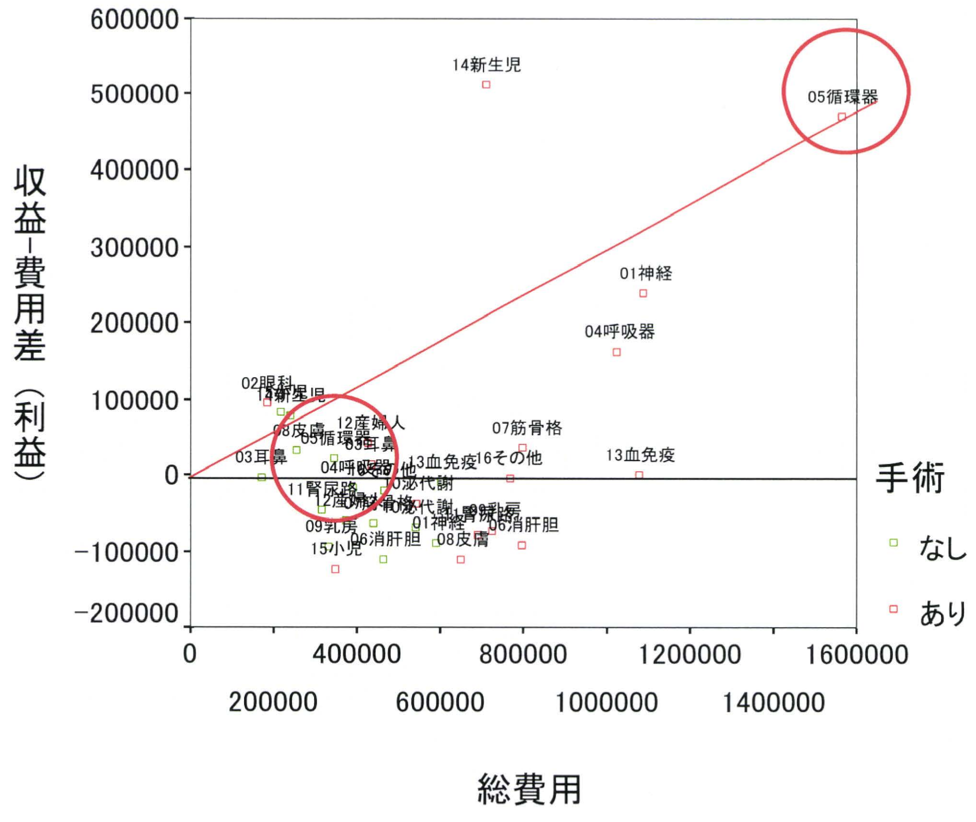


循環器領域の特徴

臓器別の収支比較



「手術あり」は黒字傾向



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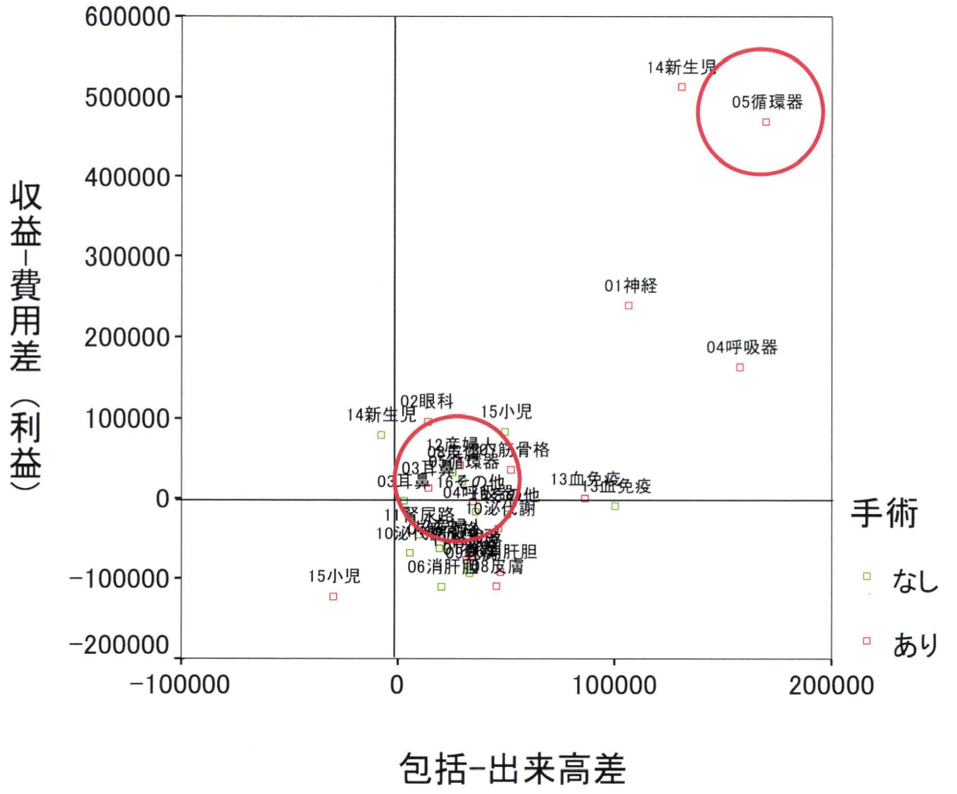
包括-出来高 差は、利益の目安になるか？



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心不全診療の特徴と
資源利用のバラツキ

原価計算からみた
循環器領域の特徴

原価計算から見た
心不全診療の特徴

DPC支払い制度における
適切な値決めに向けて

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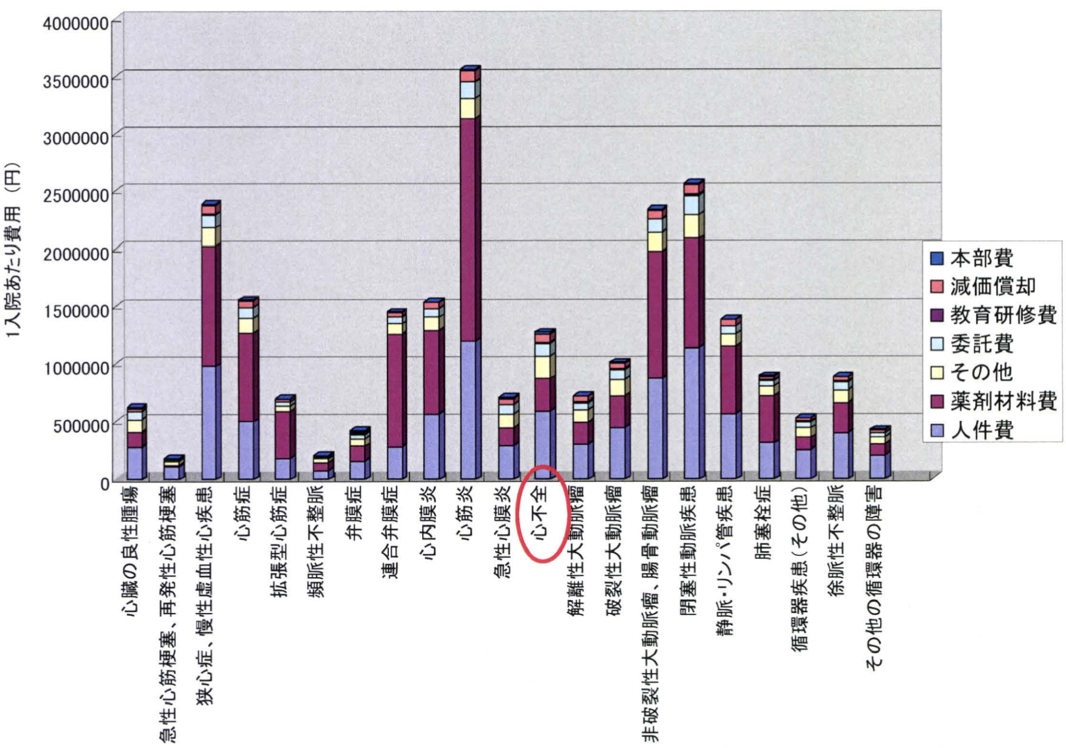
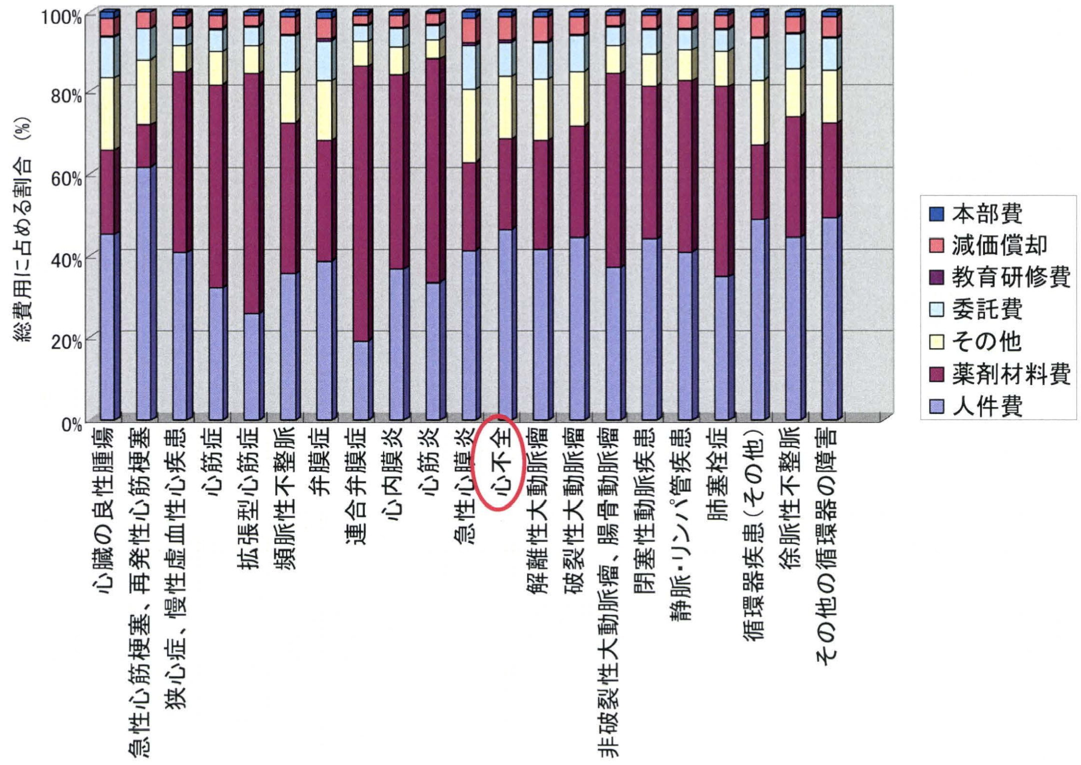
心不全診療の特徴

循環器疾患別の原価



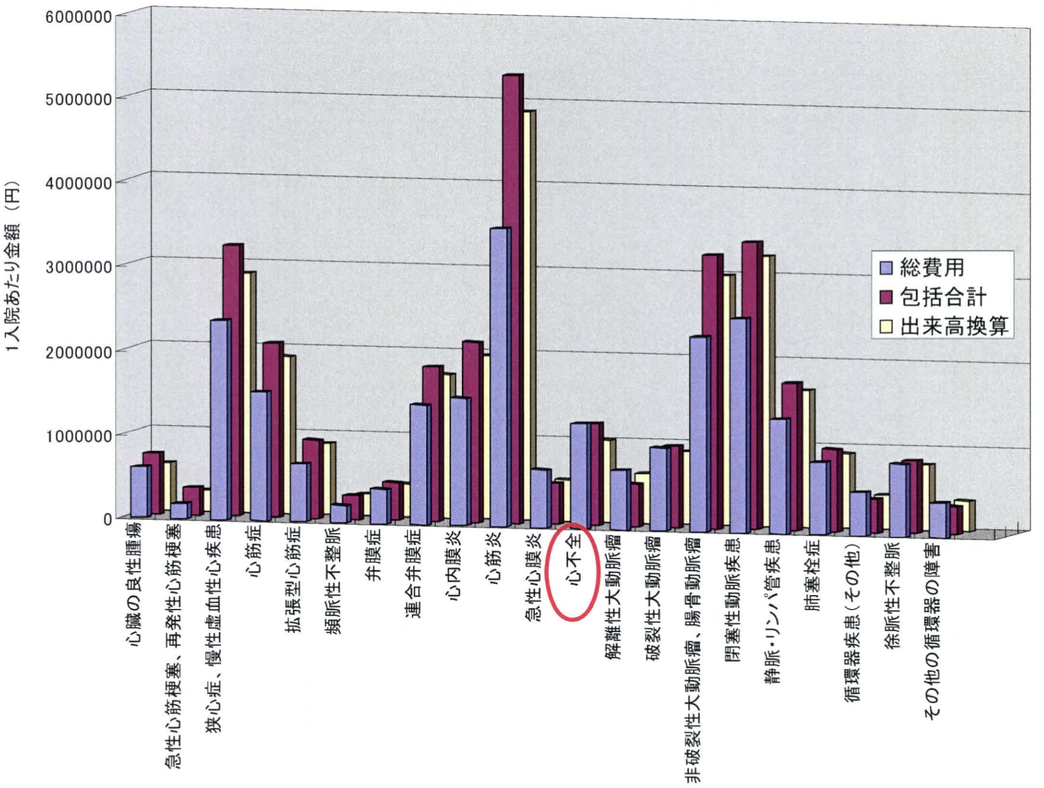
心不全診療の特徴

循環器疾患別の費目割合

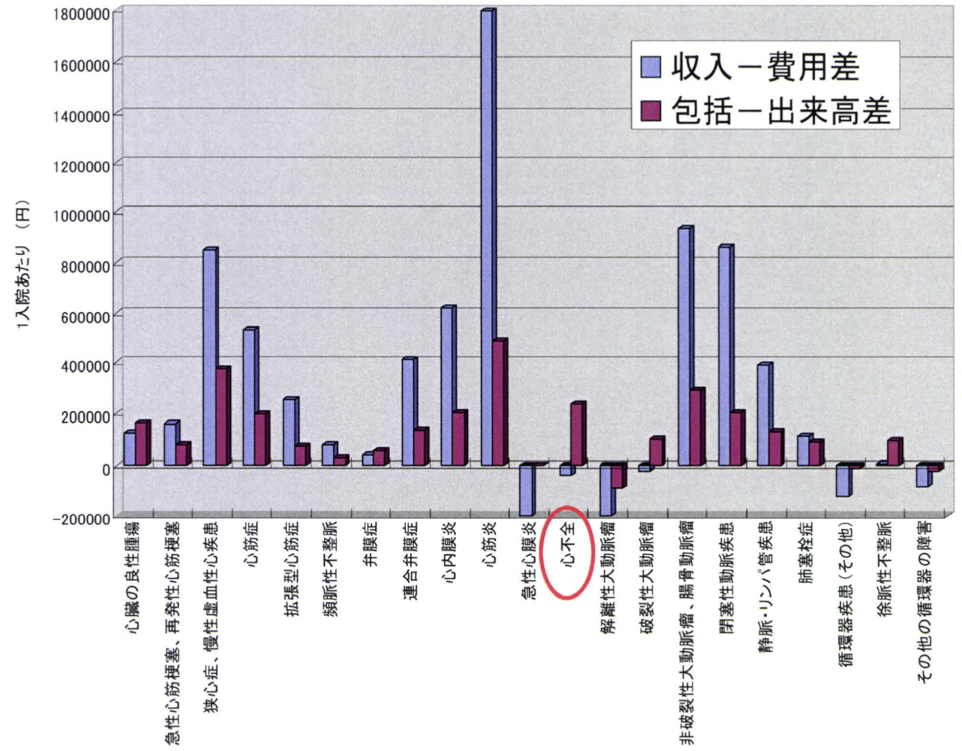


心不全診療の特徴

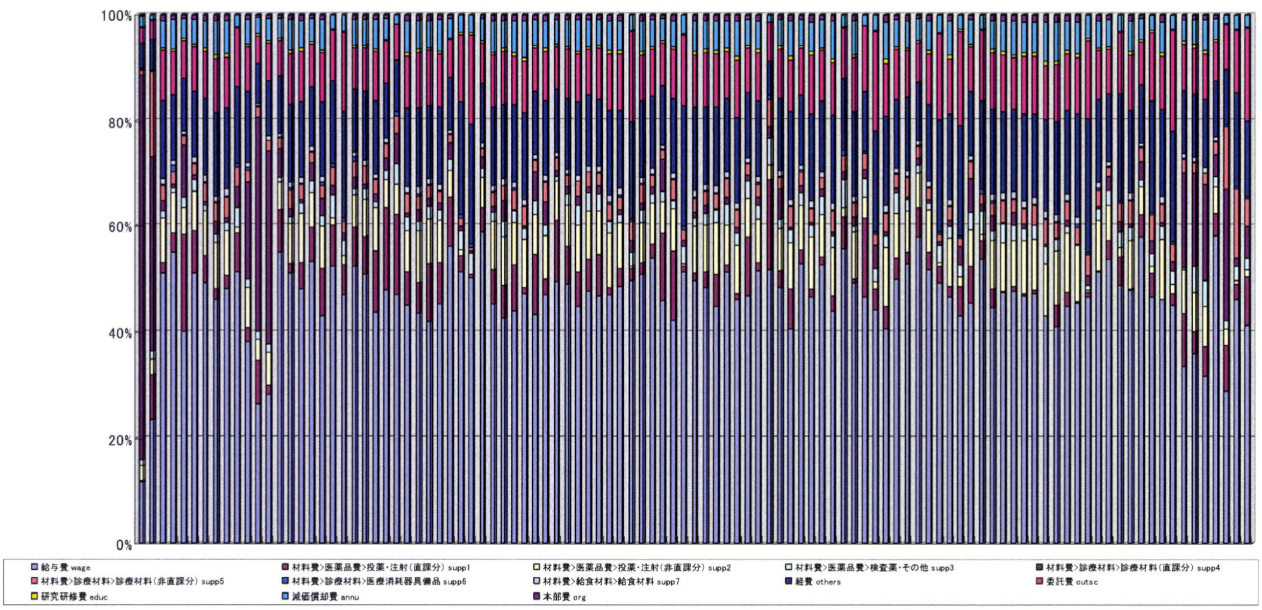
循環器疾患別の収支比較



包括-出来高差が正でも心不全診療は黒字とは限らない。



心不全　症例ごとに見た原価費目の構成



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(c) 京都大学 医療経済学分野

心不全診療の特徴と
資源利用のバラツキ

原価計算からみた
循環器領域の特徴

原価計算から見た
心不全診療の特徴

DPC支払い制度における
適切な値決めに向けて

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DPCの適切な「値決め」に向けて

- 原価計算に基づく客観的議論を。
  - 手術・手技と並んで、専門的な内科的診療技術は
    どのように評価されるべきか？
    ↑いわゆる「ドクターフィー」的要素
  - 高額な薬剤や検査は包括金額に反映されているか？
    ↑漏れのない「実施入力」が前提。
- 診療内容のバラツキ ≒ 損益のバラツキ。
  - 包括外の項目を増やすのではなく、
  - 診療の標準化をめざす方向へ

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Title: The validation of a novel method to identify healthcare-associated infections

Running Title: Validating an HAI identification method

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Summary

Despite its potential for use in large-scale analyses, previous attempts to utilize administrative data to identify healthcare-associated infections (HAI) have been shown to be unsuccessful. In this study, we validate the accuracy of a novel method of HAI identification based on antibiotic utilization patterns derived from administrative data. We contemporaneously and independently identified HAIs using both chart review analysis and our method from 4 Japanese hospitals (n=584). The accuracy of our method was quantified using sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) relative to chart review analysis. We also analyzed the inter-rater agreement between both identification methods using Cohen's kappa coefficient. Our method showed a sensitivity of 0.93 (95% CI: 0.87~0.96), specificity of 0.91 (95% CI: 0.89~0.94), PPV of 0.75 (95% CI: 0.68~0.81) and NPV of 0.98 (95% CI: 0.96~0.99). A kappa coefficient of 0.78 indicated a relatively high level of agreement between the two methods. Our results show that our method has sufficient validity for identification of HAIs in large groups of patients, though the relatively lower PPV may imply limited utilization in the pinpointing of individual infections. Our method may have applications in large-scale HAI identification, risk-adjusted multi-center studies involving cost of illness, or even as the starting point of future cost-effectiveness analyses of HAI control measures.

Keywords: cross infections, administrative data, kappa coefficient, Japan, antibiotic prophylaxis

Introduction

In addition to a substantial impact on the morbidity and mortality of patients, healthcare-associated infections (HAIs) are also associated with increased socioeconomic burdens[1-5]. The Centers for Disease Control and Prevention (CDC) has estimated 99,000 HAI-related deaths per year in American hospitals alone[6].

While the complete eradication of HAIs is an unrealistic goal, reducing preventable HAIs in hospitals would improve clinical outcomes, reduce potentially preventable medical resource utilization, as well as relieve economic burdens to patients, 3rd party payers, and healthcare providers. As patient safety and healthcare quality continue to move further into the spotlight, the ability to control HAI incidence may also provide a competitive edge for a hospital.

The methods used thus far for HAI identification in primary research may generally be categorized by the utilization of either clinical data or administrative data. For studies based on clinical data, researchers utilize patient charts or surveillance-based analyses, and therefore have access to highly detailed information. However, the labor-intensiveness associated with conducting chart reviews may place practical restrictions on the number of cases to be studied, thereby potentially limiting sample size.

In the case of administrative data, researchers use hospital discharge information to identify infections as reported by hospitals. In contrast to clinical data, the use of administrative data potentially increases sample sizes due to lower labor-intensiveness, and makes multi-institutional studies easier to conduct. This allows for inter-hospital comparisons of indicators such as length of hospital stay while adjusting for variations in patient and hospital characteristics, and the results of each hospital can be interpreted in the context of other hospitals.

HAIs are identified using administrative data through the reporting of International Classification of Diseases (ICD) codes indicative of HAIs. However, previous studies[7-8] including results from our own work[9-10] have shown that the use of ICD codes in administrative data is woefully inadequate for HAI identification.

If these inadequacies are sufficiently addressed, the use of administrative data for HAI identification may have applications in analyzing HAI burden from the hospital level to regional and even national levels. Post-identification downstream studies such as cost-of-illness analyses may also be conducted on a large scale.

Japanese administrative data includes claims data based on a national fee schedule[11], as well as information on procedures, comorbidities, as well as type, dosage and duration of antibiotics and other medications on a daily basis. Furthermore, the use of a nationally standardized hospital reimbursement system indicates that administrative data is produced in a uniform format, and this provides a convenient framework for the simultaneous study of multiple hospitals. Using this in-depth information on the utilization patterns of each patient during their hospital stay may allow us to identify cases where antibiotic utilization deviates from standardized antibiotic prophylaxis, thereby indicating the possibility of an infection.

However, variations in antibiotic prophylaxis durations within and between healthcare institutions have been shown to exist, with some hospitals adhering strictly to guidelines that advocate the minimal dosage for antibiotics, and other hospitals that exhibit a lesser degree of standardization[12]. As such, any attempts at identification of HAIs through antibiotic patterns must account for these variations in both prophylactic and non-prophylactic utilization.

In our research, we have developed a method for identifying HAIs using, in addition to the reported ICD codes in administrative data, antibiotic utilization patterns that signify HAIs. This technique was applied to a sample population of 1,058 gastrectomy patients from 10 hospitals, and resulted in the identification of an HAI incidence of 20.3%[9]. However, the accuracy of our HAI identification method has yet to be validated.

As such, the objective of this study was to validate the accuracy of our novel HAI identification method.

Methods

This study was a retrospective study using data from gastric cancer patients admitted to four Japanese hospitals for the purpose of gastrectomy. This study was approved by the Kyoto University Graduate School and Faculty of Medicine Ethics Committee (Registration Number E553).

The reliability of our HAI identification method was assessed using sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) relative to a contemporaneous chart review conducted on the same sample. Additionally, we have included Cohen's kappa coefficient[13] and prevalence-adjusted and bias-adjusted kappa (PABAK) [14] to analyze inter-rater agreement between the two different methods.

Sample size selection

The number of subjects required for this study to detect a statistically-significant kappa of 0.70 ($P \leq 0.05$) at 0.10 proportion of positive ratings, a 2-tailed test null value of 0.50, and 90% power was calculated to be 509[15-16].

Sample:

Our study originally comprised of 590 patients who underwent scheduled gastrectomies (both total and partial) due to gastric cancer from four Japanese hospitals from 2005 to 2009. After employing the exclusion criteria as described below, the actual number of patients used in analysis was 584. Candidate hospitals were recruited from participating hospitals enrolled in the Quality Indicator/Improvement Project (QIP); a program administrated by the Department of Healthcare Economics and Quality Management, Kyoto University, in which participant hospitals voluntarily provide clinical and claims data for analyses. The four hospitals used in this study were designated A to D.

Exclusion Criteria

Patients were excluded from analysis if they were minors below 20 years of age, had other surgical procedures before gastrectomy was performed, or were given antibiotics within 48 hours of admission (indicating possible community-acquired infections).

HAI Identification based on Chart Review

Both electronic and paper-based records from each of the four hospitals were analyzed. Using criteria developed by the Centers for Disease Control and Prevention (CDC)[17], HAIs were identified and categorized into infections of the urinary tract, surgical site, bloodstream, bone and joint, central nervous system, cardiovascular system, eye, ear, nose, throat or mouth, gastrointestinal system, lower respiratory tract, reproductive tract, skin and soft tissue, systemic infections and pneumonia. The CDC criteria for HAI identification were compiled into a standardized data collection and evaluation form that was used by all analysts involved in this chart review. Cases with uncertainties were discussed prior to decision-making.

HAI Identification based on Antibiotic Utilization

In addition to the clinical information obtained from the chart review, we recorded the daily antibiotic utilization and ICD-10 codes for each patient. Patients were then identified as having HAIs if the reported ICD codes indicated that an infection had occurred[8]. Patients were also identified if they fell into any of the following categories: (1) Antibiotic utilization episodes beginning from the day of gastrectomy that had durations longer than the modal duration for the hospital where the case was based; (2) Three or more antibiotic types used within a single episode of antibiotic utilization; (3) Antibiotic types changed or a 2^{nd} antibiotic type added midway during a single antibiotic utilization episode; and (4) Antibiotic utilization episodes unrelated to surgical procedures with durations greater than 4 days.

Criteria (1) to (3) were designed to provide a certain degree of flexibility with respect to variations in prophylactic antibiotic utilization patterns, while criterion (4) was designed to allow for cases where the prescribing physician ordered antibiotics for a suspected but unconfirmed infection.

Accuracy Analysis of New HAI Identification Method

The accuracy of our HAI identification method was then analyzed using sensitivity, specificity, PPV and NPV.

Furthermore, while the detailed clinical information available in patient charts would theoretically provide an infallible HAI identification method, the accuracy of identification is completely dependent on the quality of data in the patient charts. Therefore, although a chart review may represent a gold standard for HAI identification, its status as such is based on a clinical, and not a statistical, judgment. We have thus included estimates of Cohen's kappa coefficient as well as PABAK in this analysis. Kappa coefficients are conventionally used to analyze the inter-rater agreement between two unreliable raters, and as such the inclusion of these indicators provides insight into the comparative agreement between both methodologies. We calculated these based on the methods as stipulated by Cohen (1960) [13] and Byrt et al (1993) [14].

Results

Hospital and Patient Characteristics

The four hospitals used in this study included two public hospitals and two private hospitals from the Kansai region in Japan, and had a mean capacity of 620 acute care beds (range 380 ~ 902 beds). The mean age of the patients in our sample was 68.2 years at the point of admission, and ranged from 26 to 94 years. Males formed the majority of the patients, comprising 69.3% of the sample.

Infection Incidence

[Figure 1 should be placed here]

As shown in Figure 1, HAI incidence as identified by chart review under CDC-based criteria was 21.6% in total, with an inter-hospital range of 15.0% to 29.1%. The majority of these infections were surgical site infections (comprising 41.6% of the total), followed by bloodstream infections (22.0%). Urinary tract infections, gastrointestinal tract infections and pneumonia had similar incidences at approximately 11.4%~13.6% of HAIs. Other HAIs identified were skin infections, infectious hepatitis, and respiratory tract infections.

[Table I should be placed here]

Table I shows the details of HAI statuses as identified by both methods at the hospital levels and in total. Of 584 patients, 117 were identified by both methods as having had an infection, and 419 patients who had no infections during their hospitalization. It was observed that there was a tendency for more patients to be identified as infected by the administrative data method alone ("false positives") than by the chart review method alone ("false negatives"). The observed agreement between HAIs identified using our method and those identified by chart review was 91% (hospital range: 90% to 93%).

[Table II should be placed here]

An example of a case in which both methods have independently identified the presence of an infection (true positive) is provided in Table II. In this patient, our method of HAI identification showed that the antibiotic utilization patterns obtained from administrative data fulfilled two of the four infection identification criteria as outlined above. As fulfillment of a single criteria would constitute a positive infection status, this patient was flagged as infected. This evaluation proved to be correct as the patient was also positively identified as having a surgical site infection due to methicillin-resistant *Staphylococcus aureus* (MRSA), as revealed in laboratory cultures of the central venous catheter tip and drainage from the surgical site occurring within 30 days of the surgical procedure.

Sensitivity, Specificity, PPV and NPV

[Table III should be placed here]

Table III shows the sensitivity, specificity, PPV and NPV of our method of HAI identification when compared to using chart reviews for identification. The overall sensitivity and specificity of our method of HAI identification were 0.93 (95% CI: 0.87~0.96) and 0.91 (95% CI: 0.89~0.94), respectively. The overall NPV was 0.98 (95% CI: 0.96~0.99), while the overall PPV were slightly lower at 0.75 (95% CI: 0.68~0.81).

Cohen's Kappa coefficient and PABAK

The overall Cohen's kappa coefficient was calculated to be 0.78 (95% CI: 0.72~0.84; hospital range from 0.74 to 0.80). The overall bias index was low at 0.05 and prevalence index moderate at 0.51. After adjusting for prevalence and bias, PABAK was calculated to be 0.84 (95% CI: 0.78~0.90).

Discussion

In this study, we utilized chart review analysis as well as a method based on administrative data to contemporaneously identify HAIs in patients who underwent gastrectomy from four Japanese hospitals. In order to test the validity of our administrative data method, we calculated the sensitivity, specificity, PPV and NPV of the method relative to that of chart review analysis. Additionally, we analyzed the degree of non-random agreement between both methods through the use of Cohen's Kappa coefficient and PABAK.

We designed this identification method using antibiotic utilization data in response to a need for a more accurate method of identifying HAIs from administrative data[7-8]. As further proof of the inadequacy of using only hospital-reported ICD codes to identify HAIs, our current sample of hospitals reported 2 out of a possible 126 chart review-identified HAIs, or only 1.6% of the infections (authors' unpublished data).

The calculated sensitivity, specificity, PPV and NPV of our method of HAI were high, with particularly high values observed for sensitivity, specificity and NPV. The sensitivity and specificity values showed that our series of criteria using administrative data have a high probability of correctly identifying both cases and non-infected patients. The NPV was observed to be markedly higher than the PPV, at 0.98 compared to 0.75. It is possible that in addition to the presence of false positives, the relatively lower prevalence of HAI incidence may have influenced the lower PPV.

The relatively low PPV may preclude the use of our HAI identification method at the individual patient level. It should, however be noted, that the purpose of our method was not to identify infections at this level, but instead to elucidate HAI incidences and proportions in large groups of patients. As such, this method would not be likely to have any applications in prospective infection surveillance, nor would it influence the clinical treatment of a single patient. It would instead be more useful in retrospective analyses, in which the risk-adjusted economic or clinical impact of infections or the effects of infection control measures can be evaluated. Furthermore, as greater efforts to reduce unnecessary antibiotic utilization in Japan are made, these utilization patterns would become more standardized, thereby resulting in fewer false positives and increasing the PPV of our identification method.

Prior to accounting for random agreement between the two methods, the observed agreement was high at 0.91. Using the scale of interpretation provided by Landis & Koch, the overall kappa coefficient of 0.78 implies a "substantial" agreement, and in fact close to the "almost perfect" range[18]. According to Fleiss' method of interpretation, a kappa coefficient above 0.75 may be interpreted as having "excellent agreement beyond chance"[19]. After adjusting for prevalence and bias, PABAK was found to be 0.84. According to Byrt, this PABAK score indicates "very good agreement"[20]. We had included PABAK in order to address the possible difficulties associated with the interpretation of Cohen's Kappa by itself[14, 21-25]. However, care should also be taken in the interpretation of PABAK as a realistic indicator of the situation[26], as PABAK essentially assumes no bias and a prevalence of 50%, which would be extremely rare in any disease condition. Despite this, we found that Cohen's Kappa coefficient and PABAK for our study were not drastically different, suggesting that the former was relatively robust.

While Cohen's kappa coefficient and PABAK may not be direct indicators of the accuracy of our HAI identification method, they provide an alternate perspective into the degree of non-random agreement between the two methods. Our major indicators of accuracy (sensitivity, specificity, PPV and NPV) are based on the assumption that chart reviews are a comprehensive database, and that the CDC criteria are able to identify all infections. While there is no pressing evidence to suggest otherwise, the inclusion of these coefficients shows that even in a situation where chart reviews may misidentify the infection status of some patients, the high level of non-random inter-rater agreement between both methodologies supports the relative accuracy of our method.

As our criteria were based on antibiotic utilization patterns, inappropriate utilization in non-infected patients that extends beyond the parameters in our criteria would result in a false positive. While our HAI