Trends in Orthopaedic Surgery Research Using Trauma Clinical Databases: A Literature Study

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Abstract- ***Trauma clinical databases have huge amount of information about patients and their diseases. Trauma injuries are responsible for the cause of 10% of deaths worldwide. The successful development of trauma systems, including the use of trauma registries & administrative databases, played a significant role in reducing mortality and disabilities due to injuries resulted from trauma during the last few decades. Our hypothesis was that the usage of trauma clinical databases would have increased in orthopaedic surgery research. According to the literature, most of the journal articles are published by using United states databases and they are available in PubMed. As a sample, most popular 9 databases in United states were analyzed. In order to check whether the hypothesis is correct or not, research journal articles in PubMed were analyzed. PubMed was used to find the journal articles from 1990 to 2017 by using the names (or abbreviation) of the databases as search terms. We activated the filter option of the PubMed search engine during the journal articles searching period. We set the article type as journal article and publication date as 1990/01/01 to 2017/12/31.Human species was used by removing the other animals' category. The results of this study confirmed the hypothesis that database use would have increased in orthopaedic surgery research in the defined study period. Between January 1, 1990, and December 31, 2007, fewer articles using databases could be identified, whereas between January 1, 2008, and December 31, 2017, database use increased significantly. These findings conclude that the clinical databases use in the orthopaedic literature. The orthopaedic trauma clinical databases allow for evaluating current trends of adverse events in selected surgical specialties. However, variables specific to orthopaedic surgery, such as open versus closed injury, are needed to improve the quality of the results. Moreover, the data in the trauma clinical databases can be used to take decisions and testing of the biomedical devices such as orthopaedic cutting guides, External bone fracture fixators…etc.***

Indexed Terms- ***Trauma clinical databases, Clinical data, Orthopaedic surgery research, External fixators***

I. INTRODUCTION

Clinical databases have huge amount of information about patients and their diseases. The databases mainly contain patients' data, clinical consultation details, treatment data, follow up data and other information which are considered to making a final diagnostic decision by clinician. Clinical databases are widely used by Biomedical researchers to predict different diseases. Analysis of clinical databases will become an important part of orthopaedic surgery research. In addition, these studies will help us follow trends in orthopaedic practice and outcomes over time.

Trauma registries are clinical databases designed for quality improvement activities and research and have made important contributions to the improvements in trauma care during the last few decades.[1] This improvement is related to the unique advantages that trauma clinical databases offer: large clinical data samples, inclusion of patients who are representative of the country as a whole, and data that allow investigating trends in a specific period of time. We can conclude that the overview of the common uses, limitations, and methodologic considerations of databases, as well as the future of this rapidly expanding research field by analyzing orthopaedic trauma registries. [2] Moreover ,the data in the orthopaedic clinical

databases can be used to take decisions and testing of biomedical devices such as orthopaedic cutting guides ,External fixators…etc.

This overview discusses the trends in orthopaedic database research, database types, importance of analyzing clinical database and future trends in orthopaedic clinical databases. Moreover, this study was to determine how database use has changed in orthopaedic surgery research.

II. TRENDS IN ORTHOPAEDIC DATABASE RESEARCH _ UNITED STATES DATABASES

Our hypothesis was that the usage of trauma clinical databases would have increased in orthopaedic surgery research. As a sample, databases in United states were analyzed. Most of the orthopaedic databases researches have been conducted using the following nine databases in the United States.[2]

01. American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP)
02. American College of Surgeons National Surgical Quality Improvement Program Pediatric (ACS-NSQIP-P)
03. Kids' Inpatient Database (KID)
04. National Hospital Discharge Survey (NHDS)
05. Nationwide Inpatient Sample (NIS)
06. National Trauma Data Bank (NTDB)
07. Veterans Administration Surgical Quality Improvement Program (VASQIP)
08. Medicare database
09. Pearldiver database

2.1. Material & Methods

According to the literature, most of the journal articles are available in PubMed. In order to check whether the hypothesis is correct or not, research journal articles in PubMed were analyzed. PubMed was used to find the journal articles of orthopaedic surgery research from 1990 to 2017 by using the names (or abbreviation) of the databases as search terms. We activated the filter option of the PubMed search engine during the journal articles searching period. We set the article type as journal article and publication date as 1990/01/01 to 2017/12/31.Human species was used by removing the other animals' category.

The graph (Figure 1) shows the overall increase of the orthopaedic research. There is a trend in orthopaedic database research over time. (Figure 1). The National Hospital Discharge Survey (NHDS) was the first database used in orthopaedic surgery research.[2] It can be clearly identified by analyzing the first phase of the line graph (Figure 1).

The Nationwide Inpatient Sample (NIS) is the most widely used database in the orthopaedic research field (Figure 1 and 2). We can identify that the American College of Surgeons National Surgical Quality Improvement Program (ACS- NSQIP) also used to conduct the research in the last several years. Although the first database in orthopaedic surgery research is NHDS database, there is no improvement of the usage over time.

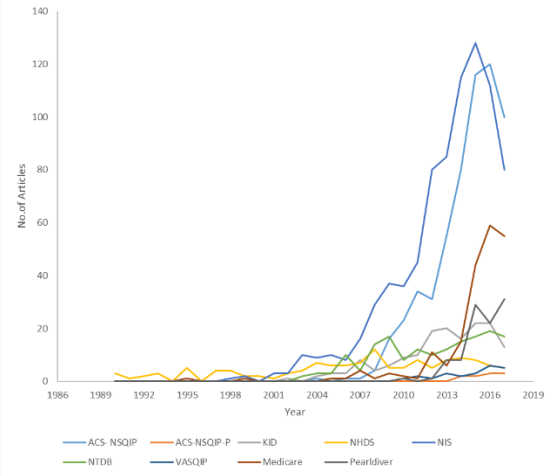

Figure No.01: Line graph of the usage of administrative and registry databases in orthopaedic surgery journal articles published from 1990 to 2017

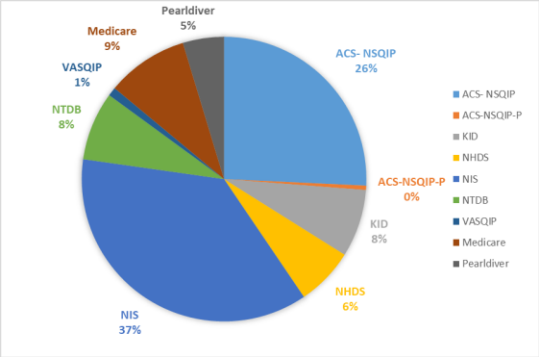

Fig.No.02: Proportions of orthopaedic surgery journal articles published from 1990 to 2017 by using each database

III. OVERVIEW OF DATABASES USED FOR ORTHOPAEDIC SURGERY RESEARCH IN CURRENT PRACTICE

There are two distinguish type of clinical databases. They are Administrative databases and Registry databases.[2] Each database has its own strengths and weaknesses.

3.1. Administrative databases

Orthopaedic surgeons and hospitals are interested in to evaluate the quality of surgical care due to increment of the expenditures of national health care. These type of evaluation can be used to reduce both perioperative morbidity and total hospital costs.[3]

Administrative databases are primarily used for the purposes of billing. It is maintained by hospitals, health insurance organizations and health maintenance government. In addition to that, Administrative databases are used to compare outcome measures among healthcare institutions to assess billing and efficacy of treatment. These type of data frequently asked by healthcare networks, payers, and regulatory and accrediting groups.[2][3] Records of health services, diagnosis information, medical procedures, patient comorbidities, patient demographics and other billing codes are included in the Orthopaedic Administrative databases. Administrative databases are a valuable resource because of their low cost, availability, massive sample size, epidemiologic insights on disparities in care, geographic and hospital variations in outcomes, and tools for risk-stratifying patients. [4] This section of the literature review of databases used for orthopaedic surgery research, presents commonly reported administrative databases and their impact on current practice.

3.1.1. Nationwide Inpatient Sample (NIS)

The Nationwide Inpatient Sample (NIS) database is a most commonly used database in orthopaedics developed by the Healthcare Cost and Utilization Project (HCUP) of the Agency for Healthcare Research and Quality. NIS database is used to publish 668 journal articles from 1990 to 2017 (Fig.No.01). The orthopaedic clinical data of the NIS database consist more than 1000 hospitals in 45 states in the United States, approximating a 20% stratified sample of all hospitals discharges. NIS database allows Researchers and policymakers to analyze and track health care–related data, epidemiological variables, costs, and hospital performance. These data are captured retrospectively and are coded using the International Classification of Disease, Ninth Revision (ICD-9). [5][6] Moreover, the orthopaedic clinical data of the NIS are recorded in such a manner that the participants are not and cannot be identified.

The NIS collect the clinical data during the entire inpatient stay. That means NIS database has only predischarge information of the inpatient. That is the main disadvantage of the NIS database. As a result, the exclusion of postdischarge events may underestimate complication rates and provides no information regarding subsequent hospital readmissions.[7][8]

3.1.2. Kids' Inpatient Database (KID)

The Kid's Inpatient Database (KID) also developed by the HCUP of the Agency for Healthcare Research and Quality. The KID is pediatric version of the NIS. It is the largest publicly available ,all-payer pediatric inpatient care database in the United States.[3] The KID has been produced every three years (2012,2015,2018…etc.). It includes only patients younger than 21 years of age. Clinical data of the KID are captured retrospectively and are

coded using ICD-9 and ICD-10 data. The first three quarters of 2015 contain ICD-9 data and the last quarter contains ICD-10.

The KID contains more than 100 clinical and nonclinical data elements for each hospital stay, including: Primary and secondary diagnoses and procedures, Patient demographics, Hospital characteristics, Discharge status, Expected payment source, Length of stay, Severity and comorbidity measures & Total charges. The KID promotes comparative studies of health services and supports health policy research on a variety of topics. Similar to the disadvantage associated with the NIS, postdischarge events are not recorded in the KID.

3.1.3. American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP)

American College of Surgeons National Surgical Quality Improvement Program (ACS- NSQIP) is the only administrative database developed and validated by surgeons.[3] [9] It is an another popular administrative database for the Researchers. It was initiated in 2005 and modeled after the Veterans Administration Surgical Quality Improvement Program (VASQIP) database.[2][10][11][12]The main aim of the ACS-NSQIP is to improve patients' safety. It includes only patients elder than 18 years of age.

The clinical data in the ACS-NSQIP includes 462 hospitals across the United States and 34 hospitals abroad, including United Kingdom, Canada, United Arab Emirates, Saudi Arabia and Lebanon.[10]This database includes more than 135 patient variables, including intraoperative data points, preoperative demographics and comorbidities,30- day morbidity outcomes and mortality outcomes in both the outpatient and inpatient and settings. Major trauma cases are not included in the ACS- NSQIP database. Data are entered online in a HIPAA-compliant, secure, web-based platform that can be accessed 24 ×7. The ACS-NSQIP database has high-quality data collection methods. It is the greatest strength of this database. At the end of the 30-day period, highly qualified risk assessment nurses review the inpatient and outpatient charts to maximize the capture of all post-operative adverse events.[11] Data go through continuous routine audits that have consistently demonstrated a high degree of reliability.

Although the ACS-NSQIP has high-quality data collection methods, it has some limitations. It has 30-day window to collect data. Moreover, important variables specific to the orthopaedic patient, such as malunion, nonunion, range of motion, pain, implant failure, external fixator failure, and other postoperative functional status are not included in the ACS-NSQIP database.

3.1.4. American College of Surgeons National Surgical Quality Improvement Program Pediatric (ACS-NSQIP-P)

The ACS-NSQIP-P database is relatively new, starting from 2012.It is the pediatric version of the ACS NSQIP and includes patients aged lower than 18 years. High quality prospective data can be collected during the data collection period. Main advantage of this database is the availability of inpatient and postdischarge follow up data. Statistician with advanced statistical software (SPSS, Stata) need for analyze this database.

3.1.5. National Hospital Discharge Survey (NHDS)

The National Hospital Discharge Survey (NHDS) was the first database used in orthopaedic surgery research. It was developed by the National Center for Health Statistics of the Centers for Disease Control and Prevention in 1965. The NHDS consists of data collected in a systematic random sample of discharges from 438 short-term, non-federal hospitals in all 50 US states. Although the NHDS represents 1% sample of discharges in the US, it is considered and weighted so that this 1% sample represent the entire US population. Hospitals are selected accordingly to represent the entire US population. The NHDS has seven diagnosis codes and four procedure codes.[13][14] The NHDS was finally discontinued in 2010 by replacing National Hospital Care Survey database. Data from the NHDS were available annually and are used by Researchers in orthopaedic.

3.1.6. National Survey of Ambulatory Surgery (NSAS)

The National Survey of Ambulatory Surgery(NSAS) is developed by Centers for Disease Control and Prevention.[15] It is a version of the NHDS, but for outpatient surgical procedures. The NSAS was first conducted from 1994 to 1996, but it was stopped due to lack of resources. It was continued again in 2006. The NSAS includes patient demographic characteristics, information on anesthesia given, diagnoses, source of payment, surgical and non-surgical procedures of patients visiting hospital-based and freestanding ambulatory surgery centers. These data are used by researchers & policy makers to find the trend in Ambulatory surgery. By definition, Ambulatory surgery means a surgery performed on a person who is admitted to and discharged from a hospital on the same day.[16]Data of Military, Federal, and Department of Veterans Affairs hospitals are not included in this database. Data are captured retrospectively and are coded using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), to identify patient diagnosis and procedures.

3.1.7. Medicare database

Medicare database is an administrative database developed by the Centers for Medicare & Medicaid Services (CMS). It is the federal health insurance program for individuals in the US who are in four different categories, including greater than or equal sixty-five years old citizens, disabled individuals less than sixty five years old, those with chronic kidney disease, and those with motor neuron disease (MND).[17]Medicare administrative claims databases are used by researchers to epidemiologic and health outcomes researches. 19.1 million Americans were covered by Medicare in 1966, and by 2015 –more than 55 million citizens were covered. Data of the Medicare databases use for describe patterns of morbidity and mortality, compare the effectiveness of pharmacologic therapies, analyze the cost of care and research on the results of important policy changes on the medical principles and results of patients.[18][19][20][21][22][23].Although Medicare is the insurance program for individuals, it claims frequently to the abundant and most complete source of inpatient and outpatient claim data, but limited to the elderly and disabled.

3.2. Registry databases

Trauma is responsible for the cause of 10% of deaths worldwide. The predictions show that in between 2000 and 2020, the Road Traffic Accidents(RTAs) will be increased by 83% in less developed countries while in developed countries they will be accounted a continuous decrease by 30%. [24]

The successful development of trauma systems, including the use of trauma registries, played a significant role in reducing mortality and disabilities due to injuries resulted from trauma during the last few decades.[1][25] Moreover, trauma registries are used to plan and conduct research, monitor trauma care and systems, establish clinical guidelines, policies & injury prevention strategies and plan resource allocation. A clinical registry contains secondary data on patients with a specific diagnosis or procedure.[26][27][28] The data are typically used for monitoring patients' outcomes to improve patient safety and quality of care. Patients are identified prior to the surgery and are followed up during the postoperative period in trauma registries. Nationwide trauma registry databases are relatively new in orthopaedic surgery research, in comparison with nationwide administrative databases. Registry databases represent huge investment in terms of infrastructure and human resources. In 2015,the direct cost of trauma registries in Australia was estimated approximately US $95 per patient.[1] [29] However, cost for the treatment of the trauma patients' cannot be reviewed due to lack of billing data in the trauma registries. Veterans Health Administration (VHA) pioneered the registry work, but since been pushed forward by the ACS.

This section of the literature review of databases used for orthopaedic surgery research, presents commonly reported Registry databases and their impact on current practice.

3.2.1. Veterans Administration Surgical Quality Improvement Program (VASQIP)

The main objective of this database is to improve the quality of care for veterans undergoing surgery, providing information to teams of health professionals for purposes of self-assessment and quality improvement.[2] Data are entered by using Veterans Health Information Systems and Technology Architecture (VistA) at the VA surgical facilities. These data are securely transmitted to the VASQIP database for compilation and analysis. Results are published quarterly and annually. Results of the data analysis are reported from the National Surgery Office (NSO) for review of surgical quality and patient care issues.

Patients at participating VHA centers across the country are identified prior to surgery using a sampling mechanism to ensure representative samples of patients undergoing each procedure with this program. Then, patients are monitored during the first 30 day (postoperative) for more than 20 different adverse event and for hospital readmission. These type of clinical data in VASQIP database have been used for orthopaedic research during last few years.[30][31] However, VASQIP database includes only patients undergoing major surgical procedures.

3.2.2. National Trauma Data Bank (NTDB)

National Trauma Data Bank (NTDB) is the largest nationwide aggregated trauma registry in the world.[32] It is an effort by the American college of surgeons (ACS) to aggregate single institution trauma registries into a nationally available database. NTDB data are used in trauma researches over the past several years. Institutions participate voluntarily, and data are entered in an NTDB format at the local hospital level. A computer system then checks the consistency of the data as it is combined in the national data set. In addition to that, inconsistent data are excluded or returned back to the local level for the improvement purpose.[2][33] The NTDB database consist of timing data including transportation to the hospital, emergency medical service response, delay to surgical intervention…. etc.[34][35] The inclusion criteria for trauma registries are NISS (New Injury Severity Score) greater than 15, a measure of the overall severity of a traumatic event, injury occurred mechanism which are particularly useful.[24] One of the major advantages of NTDB is that it allows for risk-adjusted analyzes, which are critical in assessing trauma outcomes.

Specific attributes, strengths, and weaknesses of these datasets are shown in Table 1.

Table No. 01: List of commonly used database in orthopaedic surgery research

Database	Maintained by	Data Type	Approximately cost for Raw data (US$)	Coding Scheme	Advantages	Disadvantages
Nationwide Inpatient Sample (NIS)	AHRQ HCUP	Administrative	50-500 per year	ICD-9	Nearly true nationwide sample, all ages,all ICD-9 coded outcomes	Flaws of administrative coding, lack of outpatient procedures, inpatient- only outcomes
National Trauma Data Bank (NTDB)	ACS	Administrative & Registry	$300 per year	ICD-9 and definition	Includes timing data, Both registry coded and ICD-9 coded outcomes, includes injury severity score.	Only inpatient outcomes, lack of pre-hospital events.

Veterans Administration Surgical Quality Improvement Program (VASQIP)	Veterans Administration	Registry	No charge to participating hospitals	Definitions	High quality prospective data collection , inpatient and postdischarge follow up (30 day follow up data are available)	Includes only veterans, limited types of outcomes collected
Medicare database	Centers for Medicare&Medicaid Services	Administrative	3000-20,000 per year (for all files)	ICD-9 and CPT	Enables long term follow up, includes inpatient and postdischarge follow-up	Includes only patients aged $65 yr. Expensive, flaws of administrative coding
Pearldiver database	Analytics company	Administrative	25000-50000 per year	ICD-9 and CPT	More than 30 million patients included through insurance billing records	Need statistician with advanced statistical software (SPSS, Stata)
American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP)	Civilian centers nationwide - voluntarily	Administrative & Registry	Free	CPT	High quality prospective data collection, inpatient and postdischarge follow up	Limited types of outcomes collected, Adults (aged >18 yr.)
American College of Surgeons National Surgical Quality Improvement Program Pediatric (ACS-NSQIP-P)	Civilian centers nationwide - voluntarily	Administrative & Registry	Free	CPT	High quality prospective data collection, inpatient and postdischarge follow up, pediatric specific outcomes	Limited types of outcomes collected, Pediatric (age < =18 yr.)
Kids' Inpatient Database (KID)	AHRQ HCUP	Administrative	50-500 per year	ICD-9	Nearly true nationwide sample of children; all ICD-9 coded outcomes	Flaws of administrative coding; lack of outpatient procedures; inpatient- only outcomes
National Hospital Discharge Survey (NHDS)	National Center for Health Statistics (NHCS)	Administrative	Free	seven diagnosis codes and four procedure codes	Nearly true nationwide sample; all ICD-9–coded outcomes, Publicly available files	Flaws of administrative coding; lack of outpatient procedures; inpatient- only outcomes

					from website or from National Center for Health Statistics (NCHS)	
National Survey of Ambulatory	Centers for Disease Control and Prevention	Administrative	Free	ICD-9-CM	A way to examine ambulatory procedures, All ages patients	Flaws of administrative coding; lack of inpatient procedures; no postdischarge outcomes

* AHRQ= Agency for Healthcare Research and Quality, HCUP = Healthcare Cost and Utilization Project, CPT = Current Procedural Terminology Code, ICD=International Classification of Diseases, CM= Clinical Modification, ACS= American college of surgeons.

IV. LIMITATIONS OF TRAUMA DATABASE STUDIES

The most frequent usage in orthopaedic trauma clinical data is the study of postoperative adverse event. [5][36][37][38][39] In addition to the trauma clinical databases many strengths and uses, the trauma clinical databases have several important limitations. First limitation is inpatients only nature. Such inpatients only databases (NHDS, NIS, KID…etc.) are basically administrative databases and do not collect data after discharging process. These type of databases are not captured adverse event after patient discharge. Adverse events, such as urinary tract infection and surgical site infection occur later in the postoperative period.[40][41] Therefore, analysis using inpatient only database studies are potentially misleading.

Sample dataset accuracy is depending on its population. Recent studies on documentation of comorbidities and adverse events in administrative databases, which are ICD-9 based have cast doubt.[2][42][43] Because of ICD-9 data are collected for billing purposes rather than for research purposes, a number of potential biases may be introduced. On the other hand, registry databases, such as the ACS NSQIP, are considered to be fairly accurate because the researchers devote considerable effort to documenting demographic and comorbidity data and capturing the occurrence of specific adverse events.[2][10][12] Several studies have proved that the registry databases accuracy is higher than the administrative databases. This advantage has been attributed to prospective patient identification and deliberate review of medical records for clinical research purposes.

Limited types of outcomes collected, (aged >18 yr. or age < =18 yr.) in several databases such as ACS-NSQIP, ACS- NSQIP-P. It is difficult to find the trends in an independent variable for the traumatic disorder by studying these type of databases. An additional limitation of both type of database is the cost for raw data. Participation to these type of programs is expensive, and centers must bear the costs.

Another limitation of both types of databases is the lack of specific information on orthopedics, including basic and surgical features, adverse events, functional outcomes and outcomes reported by the patients. Fracture classification, preoperative pain level, laterality of the procedure, preoperative function, and implant manufacturer and model are the missing orthopaedic-specific baseline and surgical characteristics in several clinical databases. Implant failure, screw cutout, fusion, nonunion, malunion, range of motion, and strength are the lacking orthopaedic-specific adverse events in several clinical databases.

Lack of detailed data on parameters that may be important for answering a specific study question is the another limitation of nationwide trauma clinical

database. As an example, a study on surgical site infection would benefit for selection for the best pin size of the external bone fracture fixators. Necessary data for analyze that type of selection are not available in the national databases discussed here.

V. FUTURE OF TRAUMA CLINICAL DATABASE USAGE IN ORTHOPAEDIC SURGERY

Although predicting the future, based on the presently available data is not always fully accurate, we can get some idea where the clinical databases goes.

Trauma clinical database usage for orthopaedic surgery researches have significantly improved over the past several years. It can be identified by analyzing the Figure No.01. As a result of this growth, consumers of database studies can anticipate various changes and trends. Hospitals will be replaced International Classification of Diseases, Tenth Revision (ICD-10) system by removing the ICD-9 system in the very near future. The ICD-10 system will be classified more discrete categories than does the ICD-9 system. ICD-9 system has 13,000 codes, in the meanwhile ICD-10 system has 68,000 codes. It concludes that the ICD-10 system has huge considerations than ICD-9 system. It will be advantage to the orthopaedic surgery researches to overcome several limitations of the trauma clinical database that discussed in previous section. Clinical research results still depend on the accuracy of the coding. ICD-10 system has been broadly applied and the logistics have been worked out due to consideration of the accuracy of the clinical results. Literally, we will be able to execute more subtle studies because of the greater details used to describe orthopaedic injuries in these trauma clinical databases. One potential inconvenience for researchers is handling datasets that include both ICD-9 and ICD-10 data. It should be carefully noted that no bias is introduced by the change in coding. In order to remove this type of bias issues, use data coded in either ICD-9 or ICD-10 rather than combining them. However, there will clearly be a period in which both types of data will be used.

According to the Figure No.01, Orthopaedic trauma surgery researches rapidly improved with the introduction of the registry databases (such as ACS NSQIP) as an alternative to administrative databases. This trend can be explained by the relative high quality data and relative ease of use in registry databases. It also provides valuable feedbacks on performance that is crucial to recognizing the limitation and improvement in clinical care

CONCLUSION

The results of this study confirm the hypothesis that database use would have increased in orthopaedic surgery research in the defined study period. The orthopaedic clinical databases allow for evaluating current trends of adverse events in selected surgical specialties. However, variables specific to orthopaedic surgery, such as open versus closed injury, are needed to improve the quality of the results. Between January 1, 1990, and December 31, 2007, fewer articles using databases could be identified, whereas between January 1, 2008, and December 31, 2017, database use increased significantly. These findings conclude that the clinical databases use in the orthopaedic literature. Moreover, the data in the orthopaedic clinical databases can be used to take decisions and testing of the biomedical devices such as orthopaedic cutting guides, External bone fracture fixators…etc. However, database studies are not without flaws.

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