

# BMJ Open Direct costs of osteoporosis-related hip fractures: protocol for a cross-sectional analysis of a national database

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## ABSTRACT

**Introduction** It is estimated that Iran accounted for about 1% of hip fracture burden of the world in 2007, but these data are based on incomplete evidence. As the country's population is ageing, it is expected that a dramatic rise in hip fracture incidence will result. There is no single national study that accurately estimates the incidence of all hip fractures in the country or identifies the direct costs for affected patients. To help fill this gap, the current study has been designed to determine the incidence of hip fracture associated with osteoporosis in the Iranian population and to assess the direct costs involved.

**Methods and analysis** This is a cross-sectional analysis of 2 years of hospital admissions due to hip fracture in Iran from October 2014 to October 2016 using an electronic health record called SEPAS. SEPAS is a nationwide health information system established by Information Technology (IT) and the Statistics Department of the Ministry of Health. SEPAS has recorded more than 8.5 million inpatient hospitalizations since October 2014. Our study will identify reported hip fracture data in SEPAS among admitted adult hospital patients aged  $\geq 50$  in Iran. International Classification of Diseases ICD-9 and 10 will be used as diagnostic codes. Study factors are demographic data, types of fracture, types of treatment, duration of admission, early complications, in-hospital mortality and direct cost of fracture treatment. The accuracy of the SEPAS fracture data will be ascertained through a pilot study that compares the SEPAS data with the data directly extracted from medical records of the Shariati Hospital in Tehran during the study period.

**Ethics and dissemination** The study protocol was approved by the Ethics Committee of the National Institute for Medical Research Development of Iran. Dissemination plans include academic publications, conference presentations and social media.

## INTRODUCTION

Observational studies on fracture incidence and their economic impact are necessary for public health assessment and for devising preventive strategies. Half of women and one-fifth of men after age 50 years are at risk of a fracture during their remaining lifetime.<sup>1 2</sup> There are important consequences to patients who experienced a fracture such as morbidity, pain and decreased quality of life.<sup>3</sup>

## Strengths and limitations of this study

- This study is the first nationwide data analysis of osteoporotic hip fractures in Iran, the different types of fractures and their direct economic costs using detailed medical records of SEPAS.
- By using the national identification number for each patient as a unique patient identifier in the current study, it is expected that the assessment of fracture incidence will be more accurate than previous studies.
- The accuracy of this national database for hip fracture was not previously tested, and in a concurrent pilot study designed as a part of this protocol, this accuracy will be evaluated.
- The study is based on inpatient data only. The data on outpatient hip fractures were not available for our national database analysis.

The cost of fractures is also remarkable.<sup>3</sup> The healthcare cost of fracture is expected to increase twice by the year 2025 and the burden of fracture will be a significant public health problem.<sup>4-6</sup>

Estimation of osteoporotic fractures in the year 2000 indicated that approximately 9 million fractures have occurred worldwide, including 1.6 million hip fractures, 1.4 million symptomatic spine fractures and 1.7 million forearm fractures.<sup>2 7</sup> These fractures are known as major osteoporotic fractures and accounted for noteworthy morbidity. Among them, hip and spine fractures are especially associated with excess mortality.<sup>2 8</sup> By 2050, due to the ageing population, hip fractures have been expected to rise to 6.26 million.<sup>9-12</sup>

Hip fracture is a thoughtful injury burden in the ageing population,<sup>13</sup> with high mortality rates of 16%–23%, during the first year after fracture.<sup>14-16</sup> Incidence of hip fracture is widely assessed by using inpatient medical records as hospital admission is required for all hip fractures, a major contributor to the fact that hip fracture is among the most expensive orthopaedic procedures.<sup>13 17-19</sup>

Incidences of hip fracture have been evaluated in several studies in different countries in the world and results show a 10-fold variation in hip fracture incidence.<sup>10</sup> This very large difference may be due to genetic variation in different ethnicities, different proportion of older residents, differences in lifestyles as well as different fracture registry methods on regional or national levels and in different calendar years.<sup>10</sup> Economic costs are also highly sensitive to the healthcare environment.<sup>3</sup> Thus, any healthcare cost assessment is typically country specific.<sup>3,20</sup> It is also expected that the burden of osteoporotic fracture will differ among countries because of different incidence rates and a different proportion of an older population.

The ageing population is rapidly increasing in developing countries, and as a result it is expected that by 2050 most of hip fractures in the world (about 70%) will occur in these countries.<sup>12,21</sup> The high morbidity and mortality, loss of independence and healthcare cost highlight the necessity to monitor the incidence rate and related healthcare costs associated with these fractures.<sup>22–24</sup> Because of this rising trend, these studies should be on the top priority list of public health assessment of developing countries.<sup>3,7,20</sup>

Considering the ageing trend of the Iranian population, the incidence of fracture is going to rise in the coming years. In the year 2010, there were an estimated 50 000 hip fractures in Iran, and it is projected that this number will increase to 62 000 by 2020.<sup>25</sup> A study of the burden of hip fracture in Iran in 2007 estimated that Iran accounted for about 1% of the hip fracture burden in the world and more than 12% of the burden in the Middle East.<sup>21</sup>

Although earlier studies provide important information about the high prevalence of osteoporosis and osteopenia in Iran, some gaps in knowledge of the osteoporotic fractures remain. To help fill this gap, the proposed study has been designed to determine the incidence of a range of fractures of typical sites associated with osteoporosis and to assess the direct costs to Iranian population.

### Proposal questions

The primary question of this nationwide data analysis is whether hip fracture is as prevalent as previously estimated and whether its direct costs are comparable to those of developed countries?

### Aims of this study

The primary objective of the study is to estimate the national hip fracture incidence rate attributable to osteoporosis for the population recorded by SEPAS.

The secondary objectives are to calculate the direct costs due to hip fracture, and to determine the factors associated with elevated costs, types of fractures, types of treatments, duration of admission, early complications and in-hospital mortality in the population covered by the SEPAS.

## METHODS AND ANALYSIS

### Study design

This is a cross-sectional analysis of a nationwide database in Iran. The research has been supported by the National Institute for Medical Research Development of Iran (Grant No. 9 40 204).

### Data source

Hospital discharge records will be analysed from SEPAS inpatient database from October 2014 to October 2016. SEPAS is a nationwide health information system established by Information Technology and the Statistics Department of the Ministry of Health. Based on our new pilot, more than 8.5 million inpatient hospitalizations have been registered by SEPAS since October 2014.

### Study population

Data will be included from fracture reports in SEPAS among admitted adult hospital patients aged  $\geq 50$  from October 2014 to October 2016. Patients with a primary or secondary International Classification of Diseases, 9th and 10th revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) diagnosis code indicating fracture of neck of femur (820.0–9, S.72.0–9), fracture of sacrum (S321), fracture of coccyx (S322), fracture of ilium (S323), fracture of acetabulum (S324) and fracture of pubis (S325), will be extracted from SEPAS. Most of these codes have been validated in the fragility fracture registry.<sup>26</sup>

Patients will be excluded if they are aged  $< 50$  years, or have any other injury with multiple trauma. Patients with pathologic fractures or patients with high-cost diseases such as cancer and chronic renal failure will be excluded to prevent the overestimation of medical costs.<sup>27</sup> A flow chart of the study protocol is shown in figure 1.

### Study measurements

Study factors that will be measured are demographic data, the incidence of fractures, types of fractures, types of treatments, duration of admission, early complications, in-hospital mortality and direct cost of fracture treatment.

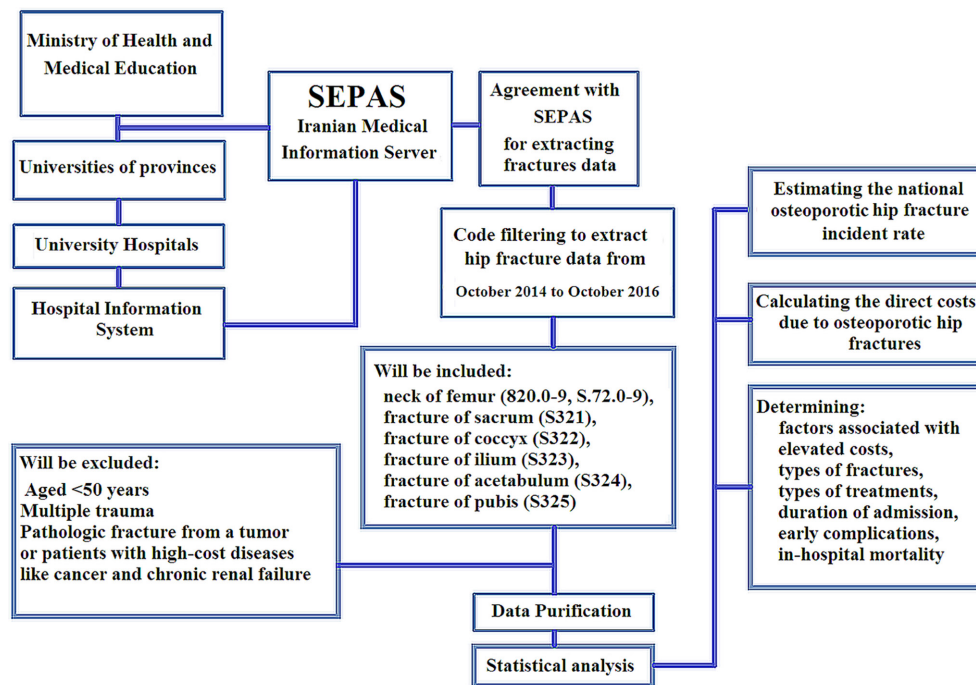
Early complications evaluated in SEPAS include postoperative complications, which are the cause of reoperation and infection such as urinary tract infections, surgical site infections and pneumonia.

The lack of a unique patient identifier is a major disadvantage for hip fracture estimation.<sup>13,28</sup> Thus, in the current nationwide analysis, the patient's national identification number will be used as a unique patient identifier.

The accuracy of the registered fracture admissions will be ascertained through a pilot study designed to compare the data from SEPAS with the data directly extracted from medical records of Shariati Hospital in Tehran.

### Cost of fractures

Direct medical costs consist of the hospital (inpatient care), physicians, nurses, anaesthesia, laboratory, implant, operation that includes the overhead cost of fluoroscopy and surgical set, medications, and readmission.<sup>3,29</sup> Costs of medicines will be determined based on the wholesale



**Figure 1** Flow chart of the study protocol. SEPAS is a nationwide health information system established by Information Technology and the Statistics Department of the Ministry of Health.

prices in 2015 that the pharmaceutical company offered to the Ministry of Health. The total expense of fracture treatment for each patient will be defined as unit fracture cost. It will be calculated by dividing the total expense by the number of patients.<sup>2,29</sup>

### Statistical analysis

Patient characteristics will be shown as a percentage for categorical variables and for continuous variables by using the mean and SD. Student's t-test will be used for analyzing the mean difference of age, direct cost and duration of admission between two types of hip fractures (intra-capsular or extra-capsular), and Fisher's exact test will be used for percentage differences of early complications and in-hospital mortality rates between types of hip fractures. Costs will be calculated as direct medical costs. Each of the medical costs will be analysed as median and range. Significant p value will set equal to or less than 0.05.

### DISCUSSION

There is a very large discrepancy of hip fracture incidence in different provinces in Iran. The annual age-standardized incidence rates in Kermanshah were 181.1/100 000 in men and 214.6/100 000 in women.<sup>30</sup> Age-standardized incidence rates for hip fracture in Shiraz were 329.57/100 000 in men and 1589.71/100 000 in women.<sup>31</sup> The largest study concerning the epidemiology of hip fracture in Iran that was published in 2006 covered only nine provinces across the country in a period of 135 days.<sup>32</sup> The current study protocol is the first nationwide data analysis of osteoporotic hip fractures in Iran. The data will be obtained from SEPAS, the largest scale health

information system nationwide in Iran. All of the hospitals affiliated with 55 medical universities in all provinces, which provide services across the country, will be surveyed for any hip fractures occurring in the study period of 2 years. Thus, the current study protocol will present the largest epidemiological study of hip fracture in Iran. Another strength of current study is using patient's national identification number as a unique patient identifier. The lack of a unique patient identifier is a major issue in hip fracture estimation.<sup>13,28</sup> The current study will also provide data analysis of different types of hip fractures, their treatments, their direct economic costs, duration of admission, early complications and in-hospital mortality using detailed medical records of SEPAS.

Previous study showed that burden of hip fracture in Iran is significant compared to all Middle Eastern countries,<sup>21</sup> with high mortality rates of 24% during the first year after fracture.<sup>33</sup> There is no detailed information about cost of hip fractures in Iran. Current protocol study has been designed to determine direct medical costs accompanied with hip fracture. This includes hospital (inpatient care), physicians, nurses, anaesthesia, laboratory, implant and operation (overhead cost of fluoroscopy and surgical set, medications, and readmission). These data will be collected for the first time in the country and would be helpful for strategic planning on hip fracture management in Iran. There are two limitations in this protocol. The first is related to the accuracy of fracture registry in SEPAS national database that has not been previously tested, and in a concurrent pilot study designed as a part of this protocol, this accuracy will be evaluated. The second is related to the outpatient data of hip fracture that were not available for our national database

analysis. It is expected that the results of this study will directly improve the accuracy of SEPAS fracture registry.

## DISSEMINATION

Dissemination plans include academic publications, conference presentations and social media. The results of this study will be communicated to the Ministry of Health and Medical Education via Center for Diseases Control and Non-Communicable Diseases Division and relevant organisations providing health services such as insurance companies. Results will also be disseminated to IT and the Statistics Department of the Ministry of Health to improve necessary procedures used to gather fracture registry records in SEPAS.

**Contributors** ZM, AH and MR conceived the study design. ZM, AH, SN, MJ, MR, RH and SM contributed to the design of data collection tools and wrote the statistical analysis plan. ZM, AH, SN and MJ monitor the data collection and analysis of the data for the whole trial. ZM, AH, RH and SM drafted the manuscript, and all authors reviewed and revised the protocol. All authors approved the final protocol to be published.

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**Competing interests** None declared.

**Ethics approval** The study protocol was approved by the Ethics Committee of the National Institute for Medical Research Development (NIMAD) of Iran.

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