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# BMJ Open Assessing the hospital volume-outcome relationship in surgery: a scoping review protocol

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## ABSTRACT

**Introduction** Even if a positive volume-outcome correlation in surgery is mostly admitted in many surgical fields, the various ways to assess this relationship make it difficult for researchers and policymakers to use it. Our aim is therefore to provide an overview of the way hospital volume-outcome relationship was assessed. Through this overview, our goal is to identify potential gaps in the assessment of this relationship, to help researchers who want to pursue work in this field and, ultimately, to help policy makers interpret such analyses.

**Methods and analysis** This review will be conducted using the six stages of the scoping review method: identifying the research question, searching for relevant studies, selecting studies, data extraction, collating, summarising and reporting the results and concluding. This review will address all the key questions used to assess the volume-outcome relationship in surgery. Primary research papers investigating the hospital volume-outcome relationship from 2009 will be included. Studies only looking at surgeons' volume-outcome relationship or studies where the volume variable is not individualisable will be excluded.

Both MEDLINE and Scopus will be searched along with grey literature. Two researchers will perform all the stages of the review: screen the titles and abstracts, review the full text of selected articles to determine final inclusions and extract the data. The results will be summarised quantitatively using numerical counts.

**Ethical considerations and dissemination** Reviews of published articles are considered secondary analysis and do not need ethical approval. The findings will be disseminated through multiple channels like conferences and peer-reviewed journals.

## INTRODUCTION

The hospital volume-outcome relationship has been discussed for years, especially in surgical disciplines. Several primary studies indicate a positive relationship between hospital volume and clinical outcomes for different surgical procedures:<sup>1-4</sup> indeed, the higher the operative volume, the better the patient's outcomes (mainly the mortality). The positive volume-outcome relationship led researchers to recommend the creation of thresholds of surgeries in order to limit

## Strengths and limitations of this study

- This scoping review will identify gaps in the assessment of the hospital volume-outcome relationship and provide future researchers with an overview of how this relationship was assessed.
- This review aims ultimately to help policy makers interpret pragmatically the volume-outcome relationship analyses based on the methodology chosen in order to help make health policy decision.
- The protocol is rigorous, the search strategy broad, and includes both peer-reviewed and grey literature, and data extraction process is clearly described.
- Quality of the papers studied was not assessed as this is a protocol for a scoping review and aims to provide an overview of the volume-outcome assessment methodology.
- By limiting our search to original English articles, we will exclude some potentially important results in other kinds of studies or languages.

centres with low activity.<sup>5,6,7</sup> These conclusions are consistent with the ones already drawn by scientific authorities as the Expert panel on Weight Loss Surgery for bariatric surgery,<sup>8</sup> or with policies implemented in a few countries such as France in 2007. These thresholds must be taken into account by policymakers when they organise the sanitary map.

Even if volume-outcome relationship is confirmed, Morch *et al's* recent systematic review pointed out the shortcomings in methodologies and suggested further research, with special attention to the methodology specific to volume-outcome relationship.<sup>4</sup> Virtually, all papers exploring the relationship used their own method: sometimes surgeon's volume is investigated and sometimes hospitals', often as a categorical value but occasionally as a continuous one. The differences in the methodologies used can have direct consequences on the conclusion of a positive volume-outcome relationship.<sup>9,10</sup> This disparity of methods makes it difficult to compare these research papers with each



other and might complicate policymakers' decisions. Even more, the way the relationship is assessed seems sometimes irrelevant. For example, considering volume as a quantitative variable implies that all the centres, except the biggest one, increase the mortality risk. The covariates used to assess the relationship can also have a major impact on the interpretation of the results. A recent study about volume-outcome relationship following cholangiocarcinoma resection showed that when adjusting the volume-effect on the travel distance, this effect was not anymore significant,<sup>11</sup> showing the importance of choosing the relevant covariates. All the aspects of the assessment of a volume-outcome relationship must be taken into account by policymakers<sup>12</sup> if they want to structure the necessary geographic mapping.

Moreover, even if high volume is associated with better outcomes across a wide range of procedures and conditions, the magnitude of the association varies greatly. Indeed, even if the volume-outcome correlation is identified, the way to set thresholds and to study this association is facing a lot of interrogation and confronting new issues. This impacts the capacity for policymakers to take this relationship as reliable information and modify the health organisation based on it.

In order to have useful and relevant information, studies should not look only for the link between outcome and hospital volume, but they should also stratify it on patients' overall health condition. Because high-volume centres are often large hospitals with specialised teams, assessing this particular link should enable sorting patients on their original seriousness in order to identify the specific impact of volume on patient outcome. It will prevent the bias of evaluating the patient recruitment more than the volume-outcome.<sup>13</sup>

Finally, although mortality is an essential outcome, it cannot be the only one sought for assessing whether a centre should be closed. According to the type of surgery explored, studies have shown that even with no effect on mortality, volume can have an impact on the length of stay of the patient,<sup>12</sup> the time to recovery,<sup>14</sup> cost of the stay,<sup>15</sup> related morbidity<sup>16 17</sup> or even disease-free survival<sup>18 19</sup> for oncological surgeries.

All of these elements are in favour of looking at the volume-outcome relationship in a wider way, including

more than just the mortality outcome or exploring volume as a continuous variable.

Our aim is therefore to provide an overview of how hospital surgical volume-outcome relationship was assessed through the key information used: outcomes explored, covariates included in the model, statistical analysis performed, gravity's assessment and so on. Through this overview, our goal is to identify potential gaps in this relationship's assessment to help researchers who want to pursue work in this field and, ultimately, to help policymakers in the interpretation of such analyses. With this goal in mind, we decided to investigate how the hospital volume-outcome relationship was assessed in studies through a scoping review, which is a form of knowledge synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence and gaps in research.<sup>20 21</sup>

## METHODS AND ANALYSIS

This protocol provides the essential procedures for conducting the review, including search strategy and articles' selection, as well as steps in analysing the obtained articles.

This scoping review method will be conducted using the six stages developed by Arksey and O'Malley<sup>22</sup> with recent advancements by Levac *et al.*,<sup>23</sup> and will be reported in accordance with Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines.<sup>24</sup>

### Step 1: identifying the research question

To meet the objectives of the study, researchers substantiated the research question:

How hospital surgical volume-outcome relationship is assessed?

This question was developed through the following ones:

- ▶ What databases were used, and what frame of reference was used to explore it?
- ▶ Which surgery and surgical disciplines were explored? What were the inclusion and exclusion criteria?
- ▶ How was the statistical analysis performed? How was the hospital-volume variable used? What kind of

**Table 1** Inclusion and exclusion criteria for surgical volume-outcome relationship relevant studies

Population	Concept	Context	Types of sources
Inclusion: studies about surgical hospital volume-outcome relationship with a sufficiently described methodology to be able to extract all data sought Exclusion criteria: only surgeon-specific volume-outcome relationship	Inclusion: every methodology used to assess surgical volume outcome Exclusion: study including the hospital volume only as a covariate in a model in which the impact of volume itself was not clearly identifiable	Inclusion: any type of surgery Any type of patient-related outcome (length of stay, mortality, morbidity, cost, ...) Any countries No exclusion	Inclusion: only primary quantitative studies will be included, written in English and published between 2009 and the data extraction date Exclusion: other designed studies

**Table 2** Keywords and query used for MEDLINE and Scopus

Database	Keywords and query
MEDLINE	Keywords: Volume, outcome, hospital, surgery, surgical, mortality, morbidity and cost Query: (“Volume-outcome” OR “Volume-mortality” OR (“hospital volume” AND (“outcome” OR “mortality” OR “morbidity” OR “cost”))) AND (“surgery” OR “surgical”) AND “hospital” NOT “surgeon” (TITLE)
Scopus	Keywords: Volume, outcome, hospital, surgery, surgical, mortality, morbidity, cost Query: TITLE-ABS-KEY (“Volume-outcome” OR “Volume-mortality” OR (“hospital volume” AND (“outcome” OR “mortality” OR “morbidity” OR “cost”))) AND “surgery” AND “hospital”) AND NOT TITLE(“surgeon”) AND (LIMIT-TO (PUBSTAGE, “final”)) AND (LIMIT-TO(DOCTYPE, “ar”)) AND (LIMIT-TO (LANGUAGE, “English”))

covariates were included in the model and how was the initial patient’s severity assessed? Which tests were used?

- ▶ How were the results presented and did the study conclude in a positive volume-outcome relationship?

### Step 2: identifying relevant studies

The review follows the Joanna Briggs Institute (JBI) methodology<sup>25</sup> to identify the suitability of articles (table 1).

According to JBI’s recommendations, both published and unpublished primary studies should be screened using the following three steps.

First, we will conduct a search on MEDLINE and Scopus databases for articles about our research topic, using “volume-outcome” or “hospital volume” keywords and look through them for the keywords used in December 2019.

After screening these articles, we will use the following keywords for the definitive query: “volume”, “hospital”, “mortality”, “morbidity”, “cost”, “outcome”, “surgery” and “surgical” (table 2), followed by analysis of the words contained in titles, abstracts, keywords and index terms to find related keywords and index terms.

After including articles, we will look for additional studies from the reference lists of all included studies and from other sources founded through personal researches. We will also search for grey literature to identify unpublished materials by using the Google Scholar database.

### Step 3: study selection

The review will be conducted by two reviewers at both stages, one is a resident in public health (ML) and the second is a doctor in medical informatics (AL). They both participated in writing the study protocol. The two reviewers will perform all the screening stages independently.

First, the literature will be screened by title and abstract according to the inclusion and exclusion criteria (table 3). Studies will be included if they have both inclusion criteria and none of the three exclusion ones.

All the papers included by either one of the reviewers will go through the next step to ensure not to exclude an interesting paper.

Finally, the full text of the articles which passed the first stage will be assessed for inclusion (figure 1). If the reviewers disagree on an article, a third reviewer who

participates on elaborating the study protocol will be involved to definitively constitute the study sample.

### Step 4: data extraction

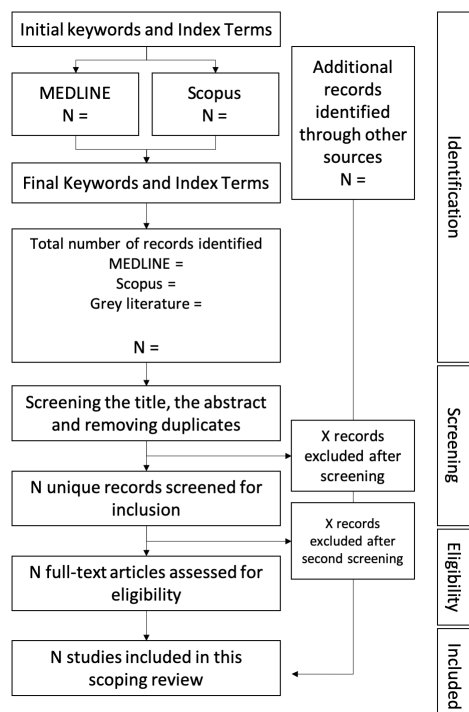
The data extraction will include the following key information about each study: author, year of publication, research design, research objectives, published or grey literature.

Details of the methodology used to assess the volume-outcome relationship will be extracted based on the principles below and according to the extraction form (table 4). The database used will be sorted into six categories as recommended by the University of Washington: electronic health record, administrative data, claims data, patient or disease register, health surveys or clinical trials data.<sup>26</sup> Studied surgeries will be addressed according to the 13 subspecialities proposed to French doctors during their initial training.<sup>27</sup> The use of International Classification of Disease to identify the study population will be screened. Inclusion and exclusion criteria are going to be noted down, and uncommon criteria will be reported in the final review. Only a narrative description will be provided for this part.

Statistical analysis method will be pointed out, such as the statistical method described by Yan *et al*<sup>28</sup> and the way of presenting the results will be classified between graphs, tables or both. Graphs will be addressed as scatter gram, line graph, bar graph, histogram, pie chart, box-plot or

**Table 3** Inclusion and exclusion criteria form

Criteria	Review result
<b>Inclusion</b>	
Surgical hospital volume-outcome relationship	<input type="checkbox"/> Yes <input type="checkbox"/> No
Methodology used precisely described (how the outcome was assessed, how the hospital volume was analysed and how the statistical analysis was performed).	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Exclusion</b>	
Surgeon volume-outcome relationship only	<input type="checkbox"/> Yes <input type="checkbox"/> No
Hospital volume used only as a covariate	<input type="checkbox"/> Yes <input type="checkbox"/> No
Publication in the form of systematic reviews, qualitative studies, editorials, letters to the editor, comments or narrative reports	<input type="checkbox"/> Yes <input type="checkbox"/> No



**Figure 1** Flow chart for search strategy and study selection.

other, as described by Slutsky *et al.*<sup>29</sup> The way the hospital volume variable is assessed will be summarised between continuous, qualitative or both. For qualitative assessment, studies will be separated according to their type of hospital volume splitting: fractals, statistical cut-off points, arbitrary or literature thresholds, and other.

Outcomes will be extracted and classified according to the frequently observed categories in literature which are mortality, cost, length of stay, readmission or others. Others will be noted down and the most frequently observed will be quoted in the review paper, as a narrative analysis. Information about how the different studies stratified their analysis on initial patients' severity will be separated between the ones using known scores like Charlson Comorbidity Index adapted by Deyo,<sup>30 31</sup> Elixhauser score<sup>32</sup> or other information. Covariates used to adjust the statistical models will also be listed and go through a narrative analysis in order to be exhaustive on what was used.

Finally, the study conclusion will be written down and sorted between positive and negative volume-outcome relationship.

Each reviewer will test the extraction data form (table 4) on the five first studies to ensure that all relevant results are extracted. If needed, the grid will be adjusted after the testing by both reviewers. Once the final grid is accepted by both the reviewers, all data will be extracted from all the papers by each of them.

### Stage 5: collating, summarising and reporting the results

After collecting all the data, descriptive results will be summarised in one table, reporting each included article. A first part of the review will describe the articles included

according to the country where the research was pursued, the journal that published the article and the year of publication. Surgeries explored and discipline concerned will also be described quantitatively. The number of databases used will be provided, along with their distribution among the six pre-identified categories.

Inclusion and exclusion criteria used in the included studies will be narratively described. The different criteria used will be summarised in a table, but no quantitative assessment will be provided.

Outcomes used will be listed along with the way they were quantitatively assessed. An analysis of the proportion of studies looking at each outcome over time will be conducted in order to identify how volume-outcome relationship research has evolved in recent years.

If possible, covariates will be listed and categorised (patient characteristics, hospital characteristics, gravity assessment, surgical precisions and so on). They will not be quantitatively assessed because our goal is to give an exhaustive overview of the variable used.

Statistical assessment, focussing on the volume-outcome relationship evaluation, will be analysed quantitatively. The most frequently observed methods will be described and precisions about them will be provided in order to help researchers to choose the most adapted method for their research question and help policymakers understand results provided in already published studies.

### Limitations

This review may suffer from limitations.

The predefined categories may be insufficient to analyse every types of studies we will include. Indeed, categories of database of subspecialties of surgery chosen or statistical methods may be in unsuitable. To overcome this limitation, the extraction grid will be tested on five studies by both the reviewers and will be adapted if needed. Besides, the 'other' category will allow the management of unforeseen cases by allowing free text entry of these new cases.

The study is limited by the number of electronic databases that will be explored: only two electronic databases will be explored (MEDLINE and Scopus) along with grey literature. By caution, we will search through Google Scholar and look for additional studies from the reference lists of all the included studies. Even though, there is a possibility that relevant literature from other databases may be missed during our researches.<sup>33</sup>

Finally, to explore the entire surgical teams' effect on patients' outcome, we have chosen to explore only the hospital volume-outcome relationship through the scoping review. This choice implies that the results will be relevant only when exploring volume-outcome relationship from a general hospital perspective, and may not be similar to surgeon's volume-outcome relationship.

This review aims to propose a broad and accurate picture of how the volume-outcome relationship in surgery was assessed, by answering all the previously stated research questions. Also, it may identify gaps in the literature for future studies on this issue. Finally, considering the

**Table 4** Data extraction form

<b>Title</b>	_____
<b>Author</b>	_____
<b>Year of publication</b>	_____
<b>Research design</b>	_____
<b>Research objectives</b>	_____
<b>Type of sources</b>	<input type="checkbox"/> Published <input type="checkbox"/> Grey literature
<b>Specific information</b>	_____
<b>1. Database used</b>	_____
	<input type="checkbox"/> Electronic health record <input type="checkbox"/> Administrative data <input type="checkbox"/> Claims data <input type="checkbox"/> Patient or disease register <input type="checkbox"/> Health survey <input type="checkbox"/> Clinical trials data
<b>2. Surgery studied</b>	_____
	<input type="checkbox"/> Head and Neck <input type="checkbox"/> Oral <input type="checkbox"/> Orthopaedics <input type="checkbox"/> Paediatrics <input type="checkbox"/> Plastics <input type="checkbox"/> Vascular <input type="checkbox"/> Thoracic and cardiovascular <input type="checkbox"/> Visceral and digestive <input type="checkbox"/> Neurosurgery <input type="checkbox"/> ENT <input type="checkbox"/> Obstetrics and gynaecology <input type="checkbox"/> Ophthalmology <input type="checkbox"/> Urology
<b>3. Use of the International Classification of Disease</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>4. Inclusion and exclusion criteria</b>	_____
<b>5. Method to sort hospitals by volume</b>	<input type="checkbox"/> Continuous <input type="checkbox"/> Categorical <input type="checkbox"/> Both
If continuous or both, precise the method used:	<input type="checkbox"/> Fractals <input type="checkbox"/> Statistical cut-off <input type="checkbox"/> Arbitrary <input type="checkbox"/> Other
<b>6. Outcomes</b>	<input type="checkbox"/> Mortality <input type="checkbox"/> Cost <input type="checkbox"/> Length of stay <input type="checkbox"/> Readmission <input type="checkbox"/> Other
If other, precise the interesting outcome studied	_____
<b>7. Severity score and covariates</b>	<input type="checkbox"/> Charlson/Deyo <input type="checkbox"/> Elixhauser <input type="checkbox"/> Other
<b>8. Statistical methods</b>	<input type="checkbox"/> One sample test <input type="checkbox"/> Two independent sample test <input type="checkbox"/> Two correlated sample test <input type="checkbox"/> More than two independent sample test <input type="checkbox"/> More than two correlated sample test <input type="checkbox"/> Correlation <input type="checkbox"/> Two categorical variables <input type="checkbox"/> Same categorical outcome on matched pairs <input type="checkbox"/> Linear multiple regression <input type="checkbox"/> Other
If other, precise	_____
<b>9. Results' presentation</b>	<input type="checkbox"/> Graph(s) <input type="checkbox"/> Table(s) <input type="checkbox"/> Both
If graph or both, its precise typology	<input type="checkbox"/> Line graph <input type="checkbox"/> Bar graph <input type="checkbox"/> Scatter gram <input type="checkbox"/> Histogram <input type="checkbox"/> Pie chart <input type="checkbox"/> Boxplot <input type="checkbox"/> Other
<b>10. Conclusion: positive volume-outcome relationship</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No

meaning of the findings as they relate to the overall study purpose, and after discussion of advantages and disadvantages of each point, implications for future research practice and policy will be discussed.

#### Patient and public involvement

No patient involved.

#### Ethical considerations and dissemination

Reviews of published articles are considered secondary analysis and do not need ethical approval. This protocol reports a rigorous methodology.

This review aims to improve the way of assessing the volume-outcome relationship in surgery by summarising how it was already performed and by identifying gaps in knowledge and research. The findings will be disseminated through multiple channels like conferences and peer-reviewed journals and may help future research. The results may also add substantial data supporting new policies.

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**Contributors** ML led the design and conceptualisation of this work, and developed the search strategy with AL. ML and AL wrote the manuscript. RM served as an expert in designing the study protocol. RM, LL and BV provided feedback, finalised the manuscript and edited the final manuscript. All authors approved the final manuscript.

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