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ORIGINAL ARTICLE

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Difficult epidural placement in obese and non-obese pregnant women: a systematic review and meta-analysis

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ABSTRACT

Introduction: The increasing rates of obese pregnant women who receive epidural analgesia during delivery make it necessary to evaluate the rate of epidural failure and difficulties during epidural placement in these women.

Methods: PubMed, Embase, Medline and Google scholar were searched systematically until December 2017 for articles reporting epidural failure and/or difficulties in epidural placement in obese pregnant women and non-obese pregnant women. We excluded studies that used ultrasound during epidural placement. Outcomes were defined as first-pass success or multiple attempts. Quality assessment of the literature was performed in accordance with an adjusted Newland-Ottawa Scale. Two groups of women were defined (body mass index (BMI) $\geq$30 kg/m^2 and BMI <30 kg/m^2). Statistical analysis was performed using OpenMetaAnalyst software.

Results: Initially 221 articles were identified, of which we included eight in the systematic review and four in the meta-analyses. Five out of six studies reported an association between BMI and epidural failure and four out of five studies reported an association between BMI and difficult epidural placement or multiple attempts. The odds ratios (OR) for epidural failure were 1.82 [95% CI 1.23 to 2.68] and for multiple attempts 2.21 [95% CI 1.39 to 3.52], both of these ORs applying to obese pregnant women compared to non-obese pregnant women.

Conclusion: The findings suggest that obesity in pregnant women increases the risk of epidural failure and difficult epidural placement during delivery at least two-fold, and that this risk increases with increasing BMI.

Keywords: Epidural; Analgesia; Body mass index; Labour; Complications

Introduction

The rising rate of obesity is of worldwide concern. It is predicted that by 2022, 80% of American adults will be overweight or obese[1] and obesity is now the most prevalent threat for a healthy pregnancy outcome.[2] Of the four million women who give birth in the United States (US) each year, an estimated 1.6 million receive epidural analgesia during delivery.[3] Obesity-related diseases such as pre-eclampsia, diabetes, cardiopulmonary diseases and obstructive sleep apnoea reduce the safety margin of anaesthetic drugs in obese parturients.[4]

General anaesthesia is associated with a higher risk of maternal complications at caesarean delivery and neuraxial anaesthesia is generally preferred, particularly for obese women in whom airway management is more difficult[5,6] and in whom caesarean delivery is more likely.[7] An optimally functioning epidural catheter in place for labour analgesia can be used for an emergency caesarean delivery, and therefore it is important that epidural placement is initially performed successfully.

Epidural catheter placement and administration of analgesic drugs can result in dural puncture, which may lead to hypotension.[8] The incidences of these complications rise with increasing body mass index (BMI).[9,10] The literature is divided regarding the incidence of post-dural puncture headache in obese women compared to non-obese women.[11,12] If epidural placement fails, opioids may be given intravenously but can cause cardiovascular and respiratory conditions, particularly in the obese.[5]

Palpation of landmarks for neuraxial techniques may be difficult in the obese parturient and the epidural space is deeper.[13] Both these factors make epidural catheter placement more difficult and more likely to fail.

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Some studies in morbidly obese women have found a greater incidence of failed neuraxial anaesthesia with need for conversion to general anaesthesia during caesarean delivery.[14–16] Little strong evidence is published on this topic.[17] Ultrasound imaging can guide epidural catheter placement in obese pregnant women[18] but is not yet commonly used. The aim of this systematic review was to assess if difficult epidural placement in labour is related to the degree of maternal obesity.

Methods

Search strategy

An English literature search for studies describing the association between pregnant obese women and difficult epidural placement was conducted using the Pubmed, ClinicalTrials.gov, Embase, Medline and Google Scholar databases. All eligible studies published prior to December 12, 2017 were included. Two co-authors (NU and EdeJ) performed three search strings using primary medical subject headings (Mesh) for Pubmed and two searches in the databases of Embase and ClinicalTrials.gov (Appendix 1). Google Scholar was reviewed to find any missing articles not found in the other databases. The bibliographies of all relevant articles were reviewed.

The following inclusion criteria were defined: 1. Studies written in English. 2. Studies describing the use of analgesia and/or anaesthesia through epidural injection in labouring obese versus non-obese women. 3. Studies describing difficult epidural catheter placement (the number of insertion attempts and/or catheter resites or repositionings and/or studies describing epidural failure) in obese versus non-obese women.

Articles were excluded when one or more of the following criteria were present: 1. Studies not available in full text; 2. Conference abstracts, conference proceedings, reviews, comments and case reports; 3. Studies without usable data (e.g. graphs from which no data could be extracted); 4. Studies performed on women only undergoing caesarean delivery; 5. Studies using ultrasound guidance for epidural placement; 6. Studies scoring 5/10 or 4/8 or lower on the modified Newcastle-Ottawa Quality Assessment Scale (see 'Quality assessment' below).

All identified studies were assessed for relevance from the title and/or abstract. In cases of ambiguity, a third independent reviewer (JD) made the decision. All articles of possible relevance were retrieved in full-text, screened and discussed in group meetings. Data extraction was performed by NU and EdeJ, and double checked by JD and CU.

Quality assessment

The quality of articles included in the systematic review was assessed by a modified version of the Newcastle-Ottawa Quality Assessment Scale (Appendix 2).[19] We modified this scale at specific points because certain criteria could not be used to assess our articles. For example, the scale does not provide a score if the selection of controls was drawn from the hospital community but in this review all controls must have been selected from the hospital community, since the intervention of interest was only possible in hospital. Therefore, the study was given a point when the control group was selected from the hospital community and we added a possible answer in the 'definition of controls' and 'ascertainment of exposure', and a question about procedural performance and loss of data. Comparability scoring was also changed, with all modifications described in Appendix 2. There are two separate versions for case-control and cohort studies. The maximum score for case-control studies was 10 and for cohort studies was eight. Studies were assessed individually and results compared. When there was a difference in scoring, the disagreements were discussed and criteria re-assessed.

Definition of variables

Failed epidural was defined as failure to place an epidural catheter at all or unsatisfactory epidural analgesia/anaesthesia according to, in order of importance, the labouring woman, the midwife or the anaesthetist. We considered epidural placement difficult if more than one attempt to place the epidural catheter was required, whether this involved new skin punctures at the same site or repositioning at a different spinal intervertebral space. Data in relation to this definition were taken from both the text and tables in the selected articles. Study characteristics and methodological explanations were also extracted from the selected articles in order to perform a quality analysis and compare the different studies.

Statistical methods

All measures of outcome were accepted in our analysis. We used the program Confidence-Interval-Calculator in Microsoft Excel to calculate the confidence intervals between the groups of obese and non-obese pregnant women if sample sizes were reported in the results section but the confidence intervals (CIs) were not provided. Statistical analysis was performed using OpenMetaAnalyst statistical software for Sierra 10.12. In order to compare the different outcomes, we formed two groups and defined obese pregnant women as those with a BMI $\geq 30\ kg/m^2$ and non-obese pregnant women as those with a BMI $<30\ kg/m^2$. Overall odds ratios (ORs) were calculated together with their 95%CI in order to compare studies and the random effects model was used to pool data. Statistical heterogeneity was tested using the chi-squared test.

Results

The initial search found 221 articles (Fig. 1). Two authors assessed all these articles for relevance based on the title and/or abstract and 100 articles were eligible for selection in full-text after this initial screening. Secondly, 81 articles were excluded due to study design and of the remaining 19 articles, 11 were excluded because study outcomes were not described. The main reason for exclusion was that articles did not describe the study topic.

Table 1 shows the characteristics of the eight studies. The studies were conducted in the United Kingdom (n=1), Australia (n=1), US (n=4) and France (n=2). Five were retrospective studies and three were prospective studies. Four were case-control studies, three cohort studies and one a cross-sectional study. The number of women included in the studies ranged from 20 to 13 299. The BMI calculation differed between studies. Two studies used self-reported pre-pregnancy BMI,[20,21] one calculated the BMI from the measured height and weight at the 13th week antenatal appointment,[22] and five calculated the BMI using information from a medical database during labour.[10,23–26]

Other articles were excluded because they did not provide comparable data, due to different definitions and/or different BMI scales.

The total score for quality assessment is shown in Table 1. After calculation and comparing the total scores, we decided that no studies should be excluded

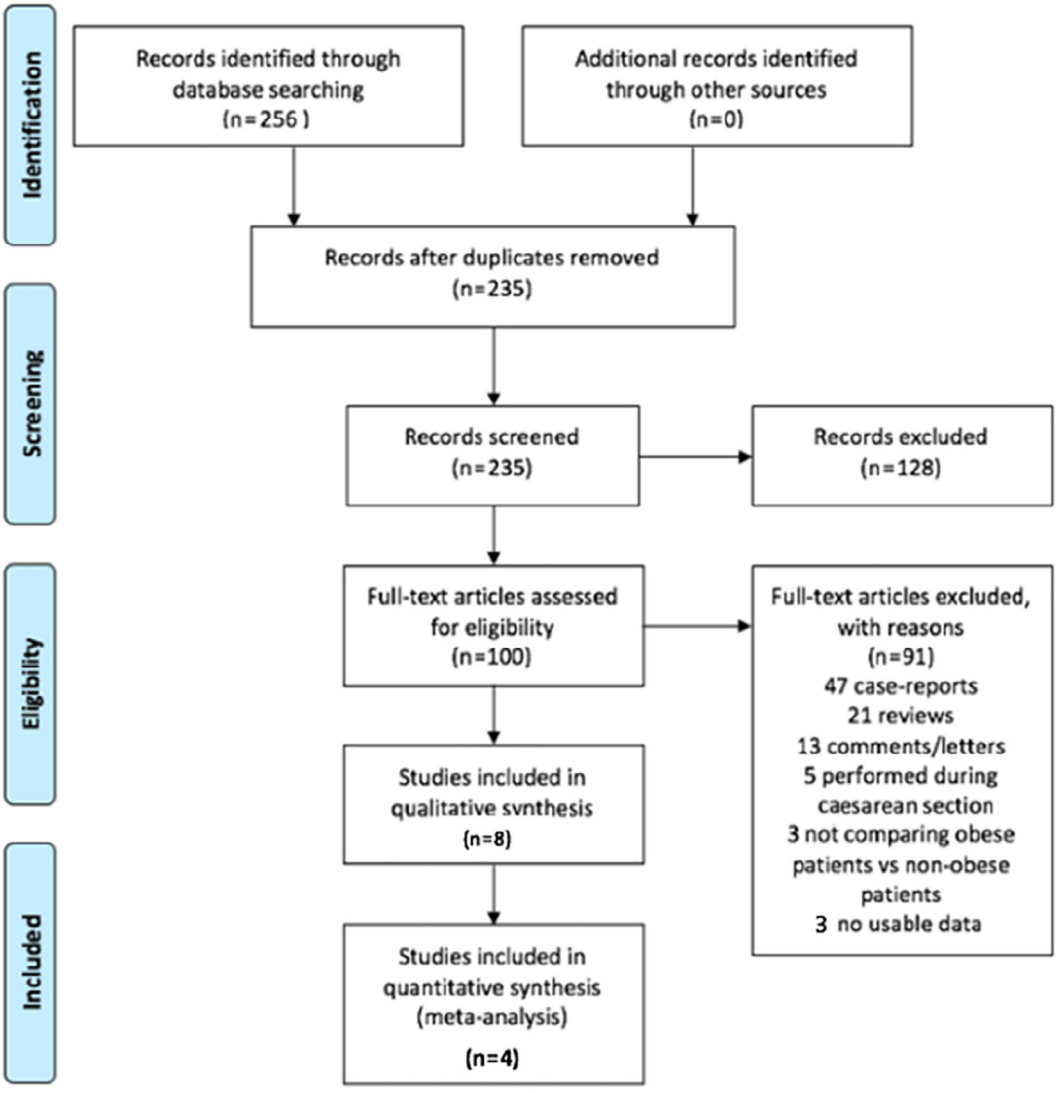

Fig. 1 Flowchart of search

Table 1 Study characteristics

Study	Country	Study design	Number of patients	BMI	Included in meta-analysis	Quality score
Eley[22]	Australia	Retrospective case-control study	126	Calculated from measured height and weight at the 13th week antenatal appointment	Yes	8/10
Tonidandel[26]	USA	Retrospective case-control study	Total data: 460 Receiving epidural: 310	Information from medical database at time of labour	No (BMI range not applicable)	7/10
Faitot[21]	France	Prospective observational study	412	Calculated BMI before pregnancy	Yes	5/8
Dresner[25]	United Kingdom	Retrospective cohort study	13 299	Weight and height reported by women, BMI calculated by anesthetists, at time of labour	No (data from time of labour)	5/8
Vricella[10]	USA	Retrospective case-control study	18 315	Calculated with information from database, at time of labour	No (data from time of labour)	6/10
Kula[24]	USA	Retrospective cohort study	2485	Information from medical database at time of labour	Yes	5/8
Bonnet[20]	France	Cross-sectional prospective study	9337	Information from medical database, prepregnancy BMI	Yes	6/8
Hood[23]	USA	Prospective case-control study	117	Information from medical database at time of labour	No (BMI range not applicable)	7/8

BMI: body mass index.

based on quality. To view our scoring on each quality assessment question per article, see Appendix 2.

Epidural failure

Five out of six studies reported a higher incidence of epidural failure in obese parturients compared to control women (Table 2). The studies did not mention complete failure to site an epidural catheter. The ORs for epidural failure varied from 1.49 [95%CI 1.21 to 1.83],[20] 2.11 [95%CI 1.37 to 3.24][24] to 5.08 [95%CI 1.05 to 24.56].[22] One study reported the maternal assessment of unsatisfactory epidural analgesia and did not find a correlation between BMI and epidural failure;[25] however, the midwife assessment of unsatisfactory epidural analgesia noted a significant correlation (OR 1.51, 95%CI 1.28 to 1.77).

Two studies examined only morbidly obese parturients,[23,26] with BMI in the obese groups of 52.6 and 53.4 respectively. Both studies found significant differences in epidural failure, with OR of 11.30 (95%CI 3.74 to 34.12) and 7.41 (95%CI 2.53 to 21.70] respectively.

Difficult epidural catheter placement

Five studies described difficult epidural placement and four were included in the meta-analyses. They described an increased incidence of difficult epidural catheter placement with increasing BMI (Table 3). Studies reported an OR for catheter repositioning in obese women of 1.37 (95%CI 1.11 to 1.69)[25] and 2.93 (95%CI 1.40 to 6.13)[22] for multiple attempts in obese women. The latter study also reported the incidence of repositioning as distinct from epidural placement attempts, as these included multiple attempts at the same site, but the difference was not significant. One study reported only the OR of difficult epidural placement, which was 2.9 (95%CI 1.8 to 4.8).[21] Kula et al. also found an OR of 1.58 (95%CI 1.17 to 2.13) for more difficult epidural placements in obese women.[24] Vricella et al. reported only median values which were not significantly different.[10]

Meta-analyses

Four studies were eligible for a meta-analysis comparing epidural failure and three studies for a comparison of difficult epidural catheter placement. We divided the groups from these studies into two categories: an obese category with BMI $\geq$30 and a non-obese category with BMI $<$30. It was not possible to define further subgroups for the degrees of obesity due to variability in the BMI categories used in different studies. For epidural failure, we regarded the maternal assessment as most important when both maternal and midwife and/or anaesthetic records were available.

Table 2 Epidural failure

Study	Type of assessment	BMI categories	Epidural failure	Odds ratio [95%CI]
Bonnet[20]	Maternal assessment	Obese: BMI ≥30 vs controls: BMI <30	Obese: 120/826 Controls: 856/8350	1.49 [1.21 to 1.83]
Dresner[25]	Maternal assessment	Obese: BMI ≥30 vs controls: BMI <30	Obese: 182/4692 Controls: 243/6833	1.09 [0.90 to 1.33]
Dresner[25]	Midwife assessment	Obese: BMI ≥30 vs controls: BMI <30	Obese: 356/6461 Controls: 289/3581	1.51 [1.28 to 1.77]
Eley[22]	Anaesthetic records	Obese: BMI >40 vs controls: BMI <30	Obese: 9/63 Controls: 2/63	5.08 [1.05 to 24.56]
Hood[23]	Anaesthetic records	Morbidly obese: BMI 52.6 ± 6.0 vs controls: BMI 27.8 ± 5.8	Morbidly obese: 33/79 Controls: 4/67	11.30 [3.74 to 34.12]
Kula[24]	Anaesthetic Records	Obese: BMI ≥30 vs controls: BMI <30	Obese: 78/1390 Controls: 30/1095	2.11 [1.37 to 3.24]
Tonidandel[26]	Anaesthetic records	Morbidly obese: BMI 53.4 ± 6.6 vs controls: BMI 31.1 ± 5.4	Morbidly obese: 28/163 Controls: 4/147	7.41 [2.53 to 21.70]

BMI: body mass index (kg/m^2).

Table 3 Difficult epidural catheter placement

Study	Type of assessment	BMI categories	More than one attempt/resite or repositioning	Odds ratio [95%CI] or median [interquartile range] (*P*-value)
Dresner[25]	Midwife assessment	Obese: BMI ≥30 vs control: BMI <30	Obese: 155/4692 Control: 210/8607	OR: 1.37 [1.11 to 1.69]
Eley[22]	Anaesthetic records: number of attempts ≥2	Obese: BMI >40 vs control: BMI <30	Obese: 34/63 Control: 18/63	OR: 2.93 [1.40 to 6.13]
Eley[22]	Anaesthetic records: resites	Obese: BMI >40 vs control: BMI <30	Obese: 10/63 Control: 3/63	OR: 3.77 [0.99 to 14.44]
Faitot[21]	Anaesthetic records	Obese: BMI ≥30 vs control: BMI <30	Obese: 40/86* Control: 76/326*	OR: 2.9 [1.8 to 4.8]
Kula[24]	Anaesthetic records	Obese: BMI ≥30 vs control: BMI <30	Obese: 135/1390 Control: 70/1095	OR: 1.58 [1.17 to 2.13]
Vricella[10]	Anaesthetic records	Obese: BMI ≥40 vs control: BMI ≤25	-	Median: 1 [1 to 1] (0.1)

*Data received from author Dr H. Keita-Meyer. BMI: body mass index (kg/m^2).

We were not able to include three studies in the meta-analysis for difficult epidural catheter placement because the study population could not be divided into these categories[10,23,26] and only catheter repositioning was reported.[25] This latter study was also not included in the epidural failure meta-analysis because the BMI had been measured at the time of labour and it was not known if these women had a BMI ≥30 before pregnancy.

There was another study which measured BMI only at the time of labour. However, the range in weight in the groups in this study was very small[24] and those women with a BMI ≥30 had a mean weight of 97.4 kg with a standard error of 0.5 kg. Thus, we calculated the BMI based on the average height of the group (64.4 inches or 163.5 cm) and assumed that if they had gained no more than the maximum 'normal' weight gain during pregnancy,[27–28] these women would not have had a BMI <30 before pregnancy. As these labouring women met our pre-pregnancy defined BMI categories, they were included the meta-analysis.

Three studies reported incidences of epidural failure and/or multiple catheter placement attempts, which made it possible to recalculate the OR and CI.[18,20,22] One study only reported an approximated OR and 95%CI[21] and, as no incidences were reported, we

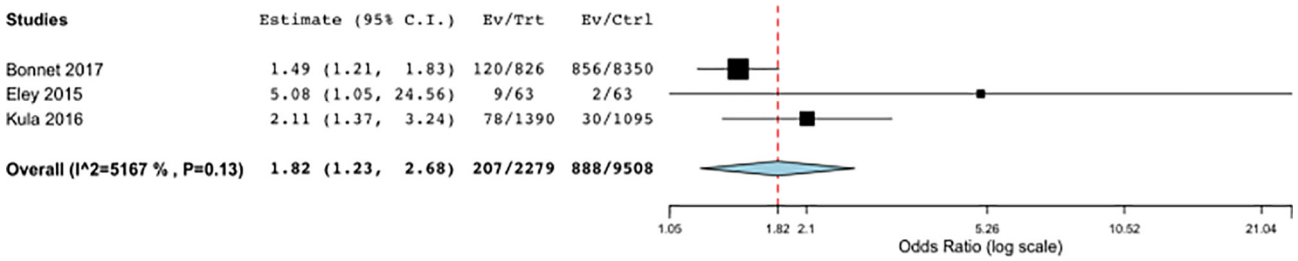

Fig. 2 Meta-analysis epidural failure

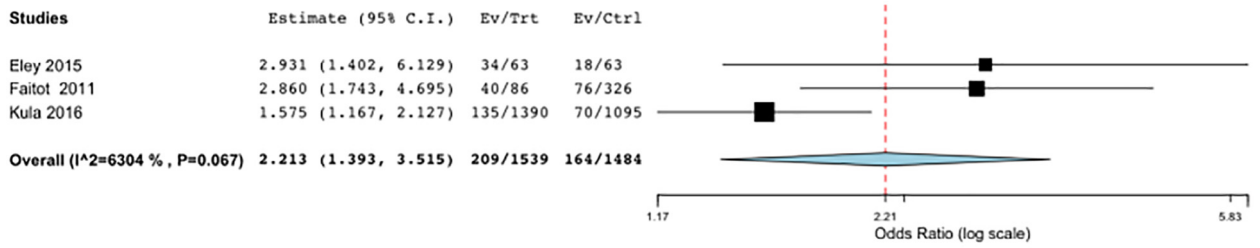

Fig. 3 Meta-analysis multiple epidural attempt

contacted the corresponding author of this study and received additional data. The n-values of the studies and the group size of the articles are shown in Table 3.

The OR for epidural failure was 1.82 (95%CI 1.23 to 2.68) (Fig. 2), which implies that obese pregnant women have a 1.82 times gretaer chance of epidural failure during labour compared to pregnant women with a BMI <30 (chi-squared test I^2 51.67%, P=0.13).

The OR for multiple epidural catheter attempts was 2.21 (95%CI 1.39 to 3.52, Fig. 3) which implies that obese pregnant women have a two-fold chance of requiring multiple attempts of epidural placement during labour compared to pregnant women with a BMI <30 (chi-squared test I^2 65.35%, P=0.06).

Discussion

This systematic review found that obesity or morbid obesity in pregnant women increases the chances of multiple epidural catheter placement attempts and epidural failure. The risk of difficult epidural placement is 2.6 times higher for pregnant women who are obese compared to non-obese pregnant women. For epidural failure, the risk is 1.5 times higher for obese pregnant women compared to non-obese pregnant women. For morbidly obese pregnant women, insufficient data were available to perform a meta-analysis. However, the two studies performed on morbidly obese patients found significantly greater ORs for difficult epidural placement.[23,26]

The studies used in this systematic review reported, non-systematically, on outcomes related to epidural placement other than epidural failure, catheter resiting and difficult placement. One of the most frequently reported of these other outcomes was dural puncture. Kula et al. reported that dural puncture did not occur more often in obese women than in non-obese women.[24] Tonidandel et al. reported a dural puncture incidence of 2% in morbidly obese women but no dural punctures in the non-obese group.[26] Eley et al. reported one dural puncture in an obese woman and none in the control group.[22] Intravascular placement was also reported (3 of 63) and occurred equally in both groups. Extension failure, defined as the use of an alternative neuraxial technique or the administration of general anaesthesia, was mentioned by Eley et al. who reported that obese women have a higher risk (31.7% vs 15.9%, P=0.04).[22] Tonidandel et al. mentioned that one morbidly obese patient needed a redose, defined as extension failure, and that no patients in the control group required a redose.[26] Kula et al. noted that more obese women needed clinician-administered epidural boluses than non-obese women (41.5% vs 35.1%, P <0.001).[24] More morbidly obese women needed catheter manipulation, with partial withdrawal of the catheter and administration of

additional local anaesthetic to treat unilateral block for pain (21% vs 11%).[26]

Hypotension was reported in one study and it was found that morbidly obese women had post-epidural hypotension more frequently than non-obese controls (systolic hypotension 16% vs 4%, P=0.003 and diastolic hypotension 49% vs 29%, P=0.002).[10] Epidural medications were described in only two studies, namely bupivacaine 0.1% and levobupivacaine 0.0625% in combination with fentanyl 2 μg/mL[21] and bupivacaine 0.125%, fentanyl 7.5 μg/mL and epinephrine 5 μg/mL.[10]

This systematic review is the first to focus on the epidural procedure in obese women during labour, an area in which limited research has been performed. Of the available literature, 35% consisted of case reports. Although not part of this review, these descriptions show that epidural catheter placement in obese women may lead to complications, particularly when conversion to general anaesthesia is required.

No standard quality assessments were applicable to this type of article, so we adjusted the Newcastle-Ottawa Quality Assessment Scale for our purpose. This enabled an assessment of the quality of research and all of the articles included scored enough points to be considered of adequate quality. We noticed that information about the loss of data or the volume of deliveries in the study period was often missing, making it impossible to exclude selection bias. The BMI was also calculated inconsistently and at different time-points, with self-reported values,[20,21] measurements at an antenatal appointment[22] or at the time of labour.[10,23–26] It is preferable that BMI is measured prior to or at the beginning of pregnancy rather than at the end of pregnancy. Nevertheless, in the meta-analyses all studies were comparable. Only the study by Kula et al. measured the BMI at the time of labour[24] but because the BMI range was very small we were able to include this study. The BMI categories used in the studies were different, which sometimes made it difficult to compare the studies directly and impossible for morbidly obese women. By taking the definition of obesity as a BMI $\geq$30 we looked for the possibility of an increased risk of multiple epidural placement attempts as a result of obesity.

This systematic review has other limitations. First, we excluded two articles because no data could be retrieved from the text.[29,30] Both concluded that there was no association between obesity and difficulty of epidural catheter placement but one study did not provide data on epidural attempts other than a graph from which numbers or percentages could not be extracted.[29] The results were also contradictory: based on their model the significant predictors of multiple epidural placement attempts were 'palpation' and 'back flexion' and not BMI, yet BMI was regarded a strong predictor of those two variables. The other article provided tabulated data from which the rates of difficult placement could not be correct when compared to the number of women receiving an epidural.[30] Another study was excluded as it contained insufficient data to enable a comparison with other studies.[31] It did not report when the BMI was measured and used a conservative OR because none of the patients in the control group had multiple attempts of epidural placement; this led to a very high OR without information as to how the calculation was performed.

Publication bias was not assessed and heterogeneity was found in the meta-analyses (Figs. 2 and 3). Both heterogeneity measurements were non-significant. By comparing only articles with similar definitions of multiple attempts, rather than by also including catheter resiting, we attempted to reduce heterogeneity and kept BMI categories between studies similar by excluding results from morbidly obese patients. In the epidural failure meta-analysis, Eley et al.'s study had a small sample compared to the other studies, which made the confidence interval very wide.[22] With the limited amount of research done on this subject and the variation in BMI categories used, it was not possible to make a better estimation of the ORs applicable to obese women.

There are several possible causes of the heterogeneity when comparing these studies, the two most important apparent confounders being the experience of the operator placing the epidural catheter and the method of data collection. Other possible confounders are the type of co-medication, the location of insertion and the time of the day of placement. Finally, there could be inherent bias when dealing with a morbidly obese parturient. The anaesthetist might think they will fail in advance. We think that, if such a mindset is an influential factor for the incidence of epidural failure, this may be based on previous personal experience. It would still be necessary to consider changing the way an epidural catheter is placed in morbidly obese patients.

We conclude that obesity increases the risk of epidural failure and the risk of difficult epidural placement in pregnant women. However, caution is needed in interpreting this conclusion, as research is limited and of poor quality: the study groups in most studies were small and data was often retrospective. We suggest that in future studies, the BMI categories should be standardised to allow better comparisons. Obesity not only increases the risk of labour complications[32] but also appears to be a cause of epidural failure and difficult epidural placement. Ideally it should be managed prior to pregnancy to minimise these risks, although this has

proven difficult.[33] If weight loss is achieved, the incidence of difficult epidural placement might decrease.

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Appendix 1. Newcastle-Ottawa Quality Assessment Scale,[19] adapted version:

Note: A study can be awarded a maximum of one star for each numbered item within the Selection, Comparability and Exposure categories.

Case control studies

*Selection (maximum score ****)*

(1) Is the case definition adequate?
(a) yes, with independent validation *
(b) yes, for example record linkage or based on self reports
(c) no description
(2) Representativeness of the cases
(a) consecutive or obviously representative series of cases *
(b) potential for selection biases or not stated
(3) Selection of controls
(a) community controls *
(b) hospital controls *
(c) no description
(4) Definition of controls
(a) the controls were defined using a BMI category *
(b) the controls were defined using a weight category
(c) no description of source

*Comparability (maximum score *)*

(1) Comparability of cases and controls on the basis of the design or analysis
(a) study controls for _____ (select the most important factors) *
(b) study does not control for confounders.

*Exposure (maximum score ****)*

(1) Ascertainment of exposure
(a) secure record (for example surgical records or medical records) *
(b) measurement of BMI by researchers or medical staff *
(c) structured interview where blind to case/control status
(d) interview not blinded to case/control status
(e) (written) self-report
(f) no description
(2) Same method of ascertainment for cases and controls
(a) yes *
(b) no
(3) The definition of the outcomes
(a) use of a commonly accepted definition *
(b) use of a definition which is clearly described *
(c) unexplained or unaccepted definition
(4) The procedure performance
(a) the procedure was performed by the same person *
(b) equally skilled staff performed the procedure *
(c) differently skilled staff performed the procedure
(d) no description
(5) Loss of data
(a) description of loss of subjects due to lacking data (mentioning numbers) *
(b) no description

Cohort study

*Selection (maximum score ***)*

(1) Representativeness of the exposed cohort
(a) truly representative of the average _____ (describe) in the community *
(b) somewhat representative of the average _____ in the community *
(c) selected group of users eg nurses, volunteers
(d) no description of the derivation of the cohort
(2) Selection of the non-exposed cohort
(a) drawn from the same community as the exposed cohort *
(b) drawn from a different source
(c) no description of the derivation of the non-exposed cohort
(3) Ascertainment of exposure
(a) secure record (for example surgical records or medical records) *
(b) measurement of BMI by researchers or medical staff *
(c) structured interview
(d) (written) self-report
(e) no description

*Comparability (maximum score *)*

(1) Comparability of cohorts on the basis of the design or analysis
(a) study controls for _____ (select the most important factors) *

*Outcome (maximum score ****)*

(1) Assessment of outcome
(a) record linkage *
(b) self-report
(c) no description
(2) The definition of the outcomes
(a) use of a commonly accepted definition *
(b) use of a definition which is clearly described *
(c) unexplained or unaccepted definition
(3) The procedure performance
(a) the procedure was performed by the same person *
(b) equally skilled staff performed the procedure *
(c) differently skilled staff performed the procedure
(4) Loss of data
(a) description of loss of subjects due to lacking data (mentioning numbers) *
(b) no description

Appendix 2.

Study	Study design	Selection	Comparability	Exposure/Outcome	Total
Eley[22]	Retrospective case-control pilot study	1: * 2: * 3: * 4: *	* study controls for delivery in the same period, age, nulliparous, gestation >39 weeks	1: * 2: * 3: * 4: – 5: –	8/10
Tonidandel[26]	Retrospective case-control study	1: * 2: * 3: * 4: –	* study controls for gravidity, parity, gestational age	1: – 2: * 3: * 4: – 5: –	7/10
Faitot[21]	Prospective observational study	1: * 2: * 3: *	–	1: – 2: * 3: * 4: –	5/8
Ray[31]	Prospective observational case-control study	1: * 2: * 3: * 4: *	* study controls for delivery in the same period	1: – 2: * 3: * 4: – 5: –	7/10
Dresner[25]	Retrospective cohort study	1: * 2: * 3: *	-	1: * 2: * 3: – 4: –	5/8
Vricella[10]	Retrospective cohort study	1: * 2: * 3: *	–	1: * 2: * 3: * 4: –	6/8
Kula[24]	Retrospective cohort study	1: * 2: * 3: *	–	1: * 2: * 3: – 4: –	5/8
Bonnet[20]	Cross-sectional study	1: * 2: * 3: *	–	1: * 2: * 3: – 4: *	6/8
Hood (23)	Prospective case-control study	1: * 2: * 3: *	* study controls for delivery in the same month, by the same obstetrician	1: * 2: * 3: * 4: –	7/8