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2 Abstract

3 Objective: To assess the incidence, risk and associated factors that contribute to an acquired
4 Surgical Site Infection (SSI) in emergency Caesarean Section (CS).

5 Design: Retrospective case-control study.

6 Setting: An acute District General Hospital in England.

7 Participants: 206 patients (101 SSI patients and 105 non-SSI patients) who had emergency
8 CS between January-December 2017.

9 Methods: Grade of surgeon, smoking status, pre-operative vaginal swab status (positive or
10 negative), diabetes status, age, body mass index (BMI), membrane rupture to delivery
11 interval and length of surgery were recorded. Risk factors were identified using simple and
12 multiple logistic regression.

13 Results: BMI (kg/m^2) was significantly associated with SSI incidence (odds ratio (OR) 1.17;
14 95% confidence interval (CI) 1.11 to 1.24; $p < 0.001$). Substantive non-significant associations
15 were recorded between SSI, patient age and vaginal swab status.

16 Conclusion: BMI was the only significant risk factor for the development of an SSI in
17 emergency CS, possibly due to the impact of excessive adipose tissue on the immune
18 system and reduced effectiveness of antibiotics. Diabetes status, patient age and pre-op
19 vaginal swab status were not significantly associated with SSI in emergency CS. Improved
20 guidelines and strategies for managing at-risk patients would enable clinicians to manage
21 emergency CS patients better and reduce the risk of SSI development. The importance of

22 wound management including frequent wound cleaning, appropriate dressings, dressing
23 changes and education is highlighted. Future research on larger samples should be
24 conducted to validate these findings.

25 Key words: Caesarean section, Infectious disease: Microbiology, Risk management,
26 Gynaecological surgery: general, Health services research, Surgical Site Infection.

27

28 Introduction

29

30 Caesarean sections (CS) occur in around 1 in 4 births in the UK ¹ and are classified as elective,
31 or emergency, where the procedure is undertaken to prevent risk to the mother and unborn
32 child. Amongst the risks associated with a CS procedure is the development of a surgical site
33 infection (SSI); a serious surgical complication defined as '*a type of healthcare-associated*
34 *infection in which a wound infection occurs after an invasive (surgical) procedure*'. ² The CDC
35 (Centers for Disease Control and Prevention)³ further define SSI as an infection that occurs
36 after surgery in the part of the body where the surgery took place. Surgical site infections can
37 sometimes be superficial infections involving the skin only. Other surgical site infections are
38 more serious and can involve tissues under the skin, organs, or implanted material. The
39 development of an SSI following CS can result in permanent injury to the bladder, uterus or
40 rectum, as well as scarring, increased pain, a reduction in mobility ⁴ and extended hospital
41 stays.⁵ A severe and potentially fatal complication of developing an SSI is necrotising fasciitis
42 (NF), a rare bacterial infection affecting the soft tissue and fascia. ⁶

43 The World Health Organization [WHO] ⁷ recommended C-section rates should be between
44 10% and 15%. However, there has been a gradual international increase in the amount of CS
45 being undertaken. In the United States, CS has been highlighted as a common procedure,
46 increasing by 41% in a 13-year period to its current rate of about 32% ⁸ Similarly, high rates
47 are currently observed in the UK (26.5%) ⁹; in Australia (32.3%) ¹⁰; and in China (41%). ¹¹ In
48 other countries both the current proportion and rate of increase are high: Zejnullahu et al. ¹²
49 report that in Kosovo, the rate of CS rose from 7.5% in 2000 to 27.3% in 2015 with 33.5% of
50 deliveries in tertiary referral care services being C-sections.

51

52 The increase in CS risks an increase in SSI, with the WHO ¹³ warning that SSIs affect up to one-
53 third of patients who have undergone a surgical procedure. Almost half of SSIs reported in
54 the European Centres for Disease Prevention and Control surveillance system ¹⁴ were
55 identified as superficial, with 30% being deep, and 20% extending to organ/space. However,
56 Wilson et al. ¹⁵ reported that procedures associated with a very short post-operative stay, e.g.
57 CS, only had infections recognised and reported following discharge from hospital. These are
58 therefore likely to be underestimated, given that approximately 50% of SSIs become evident
59 after discharge. ¹⁶ Incidence rates for the development of SSI in CS have been reported
60 globally as 4.6%. ¹⁷ However, Jenks et al. ¹⁸ reporting on a multicentre English trial, concluded
61 that SSI was estimated to be just under 10% and the readmission rate due to SSI following CS
62 was 0.6%.

63

64 SSI represents a significant financial and patient burden, with costs estimated at over £2
65 billion to the UK healthcare system, with a median cost of £7,467 per SSI CS patient compared
66 to £3,572 for non-SSI CS patients. ¹⁹ Annual costs exceed US\$1.6 billion in the US ²⁰ AU\$268

67 million in Australia,²¹ and £930 million in the UK.¹⁹ Increased financial expenditure are mainly
68 attributable to increased length of hospital stay¹⁸ and excess cost per operation of £3,855,
69 with an estimated excess cost of over £7,000,000 per hospital in the UK.²² The pain and
70 isolation concomitant with suffering an SSI also significantly impacts on patient quality of life
71 and experiences of care.²³ Umscheid et al.²⁴ argue that 60% of SSIs may be preventable and
72 their risk minimised by applying best practice in the perioperative period.

73

74 The international literature has identified several risk factors that predispose an individual
75 developing an SSI following a CS procedure in general, including obesity and an increased BMI,
76 increased age, pre-eclampsia, grade of surgeon and existing comorbidities. Indeed, obesity,
77 age and pre-eclampsia have been linked to post-surgical complications, possibly
78 compounding wound healing and increasing the risk of infection.^{25, 26} Extended labour time
79 and the complexities surrounding an emergency CS also impact the possibility of post-surgical
80 infection.^{27, 28} However, there are some inconsistencies; in a multicentre study of 4107
81 women who underwent a CS at 14 NHS hospitals in England, Wloch *et al.*²⁹ found obesity
82 (defined as BMI>30 kg/m²), age <20 years and grade of surgeon to be significantly associated
83 with developing an SSI. Obesity was also found to increase the risk of SSI within 30 days after
84 CS in a case-control study of 240 women at a hospital in Ireland.³⁰ However, Najm and Majeed
85³¹ failed to find evidence to suggest that obesity was a contributing factor in SSI development
86 in a sample of 200 women in a hospital in Iraq. Poor infection control monitoring and
87 procedures may have limited the extent to which these findings are generalisable to the wider
88 population.

89

90 Although there appears to be several patient-level factors that make developing an SSI
91 following a CS more likely, the extent to which these elements increase the likelihood of
92 infection, in emergency CS is not widely scoped out. This is problematic, as a lack of evidence-
93 based guidelines contributes to inconsistencies in SSI prevention, treatment and
94 management in CS, increasing the economic burden ²² and obvious detrimental effect on
95 patient outcomes and experiences of care. Whilst evidence-based guidelines emphasise the
96 prevention and treatment of SSI ¹ there is an obvious lack of guidance for the management of
97 SSI in emergency CS. The study objective was to quantify the incidence of Surgical Site
98 Infection (SSI) in patients who have had an emergency Caesarean Section (CS), identifying the
99 risk and associated factors that contribute to the development of SSI in order to develop a
100 better understanding of the potential mechanisms that may increase the likelihood of
101 infection.

102

103 Aim

104 The aim of this study was to quantify the incidence of Surgical Site Infection (SSI) in patients
105 who have had an emergency Caesarean Section (CS), identifying the risk and associated
106 factors that contribute to the development of SSIs.

107

108 METHODS

109 A retrospective case-control study (with approximately 1:1 case: control ratio) of data from
110 individuals who had an emergency CS procedure performed between 1st January 2017 and
111 31st December 2017 at Pinderfields General Hospital, Wakefield; part of the Mid Yorkshire

112 NHS Hospitals Trust was conducted. Cases were defined to be women undergoing emergency
113 CS who experienced an SSI within 30 days of the procedure; controls were defined to be
114 women undergoing emergency CS who did not experience an SSI within 30 days of the
115 procedure. Following written approval, data was collected from the electronic databases used
116 by the Mid Yorkshire Maternity department, comprising data of all patients seen and treated
117 by Pinderfields obstetrics department.

118

119 Inclusion criteria were:

- 120 • Women who had an emergency CS performed between 1st January 2017 and 31st
121 December 2017
- 122 • Women with a positive wound swab indicating an infection less than 30 days after the
123 procedure
- 124 • Women without a positive wound swab for non-SSI cases

125

126 Exclusion criteria were:

- 127 • Any women with an infection such as sepsis that could not be traced back to an SSI
- 128 • Any women who did not have an emergency CS performed between 1st January 2017
129 and 31st December 2017
- 130 • Patients with hypothyroidism

131

132 The following variables were collected: grade of CS (categorised as 1-4), smoking status
133 (categorised as current smoker, ex-smoker or non-smoker), whether or not a pre-operative
134 vaginal swab was taken, diabetes status (categorised as non-diabetic, Type I, Type II or
135 gestational), grade of surgeon (categorised as registrar, specialist trainee, consultant, senior

136 house officer (SHO) or associate specialist), patient age, patient BMI, membrane rupture to
137 delivery interval and length of surgery.

138

139 The sample was summarised descriptively. A series of uni-variable logistic regression
140 screening analyses were conducted on the outcome of SSI status to identify variables
141 substantively associated with the outcome ($p < 0.200$); with low-frequency categories of
142 certain variables combined where appropriate. All such variables were carried forward into a
143 corresponding multiple logistic regression analysis. All analyses reported unadjusted or
144 adjusted odds ratios with associated 95% confidence intervals, p -values and the percentage
145 of correct classifications.

146

147 For inferential analysis, CS grades were merged into G1 and G2 (reference category); and G3
148 and G4. Smoking status was merged into non-smoker (reference category); and current/ex-
149 smoker. Diabetes status was merged into no diabetes (reference category); and any kind of
150 diabetes. Grade of surgeon was merged into registrar (reference category) and Other.

151 Results

152 Data was obtained from 206 emergency CS patients for the study; including 101 who had an
153 SSI and 105 who did not have an SSI. The sample is summarised in Table 1 below.

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INSERT TABLE ONE HERE

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158 Regression parameters from a series of uni-variable binary logistic regression analyses

159 conducted on all included variables are summarised in Table 2.

160

161

INSERT TABLE 2 HERE

162

163 According to the level of substantive association with the outcome, BMI, age, diabetes status

164 and pre-operative vaginal swab status were carried forward for inclusion in the multiple

165 model. Parameters from this model are summarised in Table 3.

166

167

INSERT TABLE 3 HERE

168

169 DISCUSSION

170 Findings from this study identified BMI as the only significant risk factor from a range of

171 patient-level factors for the development of an SSI in emergency CS. Interestingly, for every

172 increase in unit of BMI kg/m², the risk of SSI increased by 17%. Patient age, diabetes status

173 and pre-operative vaginal swab status were not found to be significantly associated with an

174 increased risk of SSI.

175

176 *BMI and obesity*

177 The finding that BMI poses a significant risk factor for developing an SSI following emergency

178 CS is consistent with previous research demonstrating the negative impact on post-surgical

179 infection risk ^{29, 30, 25, 27, 26}, Wloch *et al.* ²⁹ and Ghuman *et al.* ²⁷ both cited impaired immune
180 response, larger wound area size and poor perfusion of prophylactic antibiotics in obese
181 individuals as possible reasons for this increased risk. One possible explanation is the
182 pathophysiological role that BMI plays in emergency CS due to the decreased efficacy of
183 excess adipose tissue on the immune system and a decrease in perioperative tissue
184 deoxygenation. ³² There is evidence to support this; in a meta-analysis of the use of
185 perioperative supplemental oxygen therapy on the rate of SSI, Qadan *et al.* ³³ found that
186 administering supplemental oxygen following an operation had a significant effect in
187 preventing the development of an SSI, possibly due to 'oxidative killing', which requires
188 sufficient oxygen partial pressures in order to function. Metabolic and hormonal changes
189 attributable to obesity have been cited as increasing the risk of infection ³⁴ and impaired
190 wound healing ^{35, 36, 37} suggesting that the physiological impact of an increased body mass
191 compounds the body's ability to recover following a surgical procedure. However, other
192 studies have failed to substantiate these findings or indeed identify possible causes for the
193 increased risk of infection in obese patients. ^{25, 30} The impact of BMI on post-surgical
194 outcomes has been recognised more widely in general surgery as a possible consequence of
195 impaired wound healing due to increased volume of subcutaneous fat, increased tension on
196 surgical incision and elevated blood glucose levels. ³⁸ Impaired antibiotic performances and
197 altered immune cell function ^{39, 40} as well as a larger surgical incision and more complex
198 surgical procedure ⁴¹ have also been cited as explanations for the increased risk of infection
199 in obesity.

200

201 *Associated risk factors*

202 Smoking status, existing health conditions such as diabetes, age, or skin closure techniques
203 were not found to contribute to an increased risk of infection in this study. This is in contrast
204 to other research which has found significant relationships for smoking and delayed wound
205 healing,⁴² diabetes^{28, 43, 44} and skin closure techniques.⁴⁵ Indeed Henman *et al.*²⁸ found age
206 was not associated with SSI in CS; however, other evidence suggests that up to the age of 65
207 years, there is an increased risk of SSI more generally,⁴⁶ possibly due to an impaired immune
208 system.⁴⁷ An increase in age-related comorbidities could also increase the risk of developing
209 an SSI following emergency CS.⁴⁸ One possible reason for age being unrelated to SSI in this
210 study is the small age range within an already young sample. In addition, the risk factor of
211 diabetes has been identified in the literature as a risk factor for SSI due to a reduction in the
212 body's immune response to defending against microbes as well as impairing wound healing
213⁴⁹ and it is likely that hyperglycaemia, hypoxia and chronic inflammation all playing a role in
214 interrupting the different crucial stages of wound healing.⁵⁰

215

216 Limitations

217

218 This study used BMI to calculate body composition, however, the accuracy of BMI to diagnose
219 obesity has been questioned, with misclassifications evidence in the literature.⁵³ More
220 recently, the Edmonton obesity staging system (EOSS)⁵⁵ has been proposed as an alternative
221 to the simplistic measurements of BMI in guiding clinical decisions in obesity assessment and
222 management through a five-stage classification structure, accounting for the metabolic,
223 physical and psychological individual differences in adiposity-related complications. However,
224 BMI currently remains one of the most commonly used methods of body composition
225 measurement and is the rationale for its use in this study. A further limitation of the findings
226 from this study is the potential for stigmatisation by healthcare professionals (HCPs) working

227 in reproductive care, of pregnant women considered obese, ⁵⁶ particularly with the over-
228 emphasis on risks associated with being overweight pre and post pregnancy that has been
229 identified in the literature. ⁵⁷ Indeed, Ward and McPhail ⁵⁸ outline the importance of educating
230 HCPs to reduce stigmatising attitudes and beliefs about being overweight in pregnancy
231 through the adoption of a health, rather than weight focused approach to maternal care. In
232 addition, the literature suggests SSI rates are higher for repeated rather than primary CS. ⁵⁹
233 Due to the relatively small sample size it was not possible to collect sufficient data relating to
234 this variable although it is possible this variable may have had an impact.

235

236 This study utilised data collected from a single hospital in an NHS Trust and a relatively small
237 sample size may have contributed to the finding that certain patient-related factors were not
238 associated with an increased risk of SSI following CS. It was also difficult to capture data on
239 certain variables due to missing or inaccurate data recording. In addition, the identification of
240 patients with SSIs relied on wound swabs; use of swabs to identify an infection can lead to
241 both false negative results (due to decreased volume of bacteria collected by the swab, as
242 identified by Aggarwal *et al.*⁵⁴; and false positive results (when the swab becomes
243 contaminated by commensal organisms). However, alternatives such as the use of tissue
244 cultures to increase sensitivity and specificity would be more invasive for the patient,
245 therefore swabs were considered the most accurate method of identifying infection in this
246 study.

247 Implications for Clinical Practice

248

249 The possible negative effect of excessive adipose tissue on the body's immune system as well
250 as the reduced effectiveness of antibiotics in individuals with an increased BMI suggests that

251 patients in this group are most at risk of developing an SSI, possibly highlighting the need for
252 increased monitoring and surveillance of this patient group to mitigate the potential
253 development of SSI. This could be achieved through increasing the patient's awareness of
254 their increased risk and ensuring they are provided with the appropriate education about
255 possible signs and symptoms of SSI following discharge.

256 Conclusion

257

258 This study found that BMI was significantly associated with an increased risk of developing an
259 SSI in patients undergoing emergency CS. Other potential risk factors such as diabetes status,
260 patient age and pre-op vaginal swab status did not reach statistical significance in this study.
261 Future research on larger samples should be conducted to validate these findings to
262 substantially improve the knowledge and evidence base on the treatment and management
263 of SSI and associated risk factors following emergency CS.

264

265

266 Contribution of authorship:

267

268 All authors made significant contribution to the manuscript. KO was responsible for study
269 design and conception. TS, JB, JS and KO wrote the manuscript, which was developed from
270 an MRes thesis submitted to the University of Huddersfield by TS; supervised by JB and JS.
271 JS and TS conducted the statistical analysis. JB, JS and KO provided critical feedback.

272 All authors approved the final manuscript for submission.

273

274 Ethical approval

275

276 Ethical approval for this retrospective study was received from The University of
277 Huddersfield's School Research Ethics Panel: Reference: SREP-2019-061, 25th July 2019.
278 Written consent was also obtained from the maternity department at Mid Yorkshire
279 Hospital NHS Trust and approval from occupational health at Pinderfields General Hospital.

280

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282

283

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