



ROYAL COLLEGE OF
PHYSICIANS AND
SURGEONS OF GLASGOW



Intercollegiate Specialty Fellowship Examination

Generic Paper

Critical Appraisal

Note: Parts of the sections within the original article have been redacted.

Please note that the sample answer key provided has model answers and they are not exclusive. Other options could be considered as correct answers.

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Critical Appraisal

Extract – 35 marks total

Beard, D., Rees, J., Cook, J., Rombach, I., Cooper, C., Merritt, N., Shirkey, B., Donovan, J., Gwilym, S., Savulescu, J., Moser, J., Gray, A., Jepson, M., Tracey, I., Judge, A., Wartolowska, K. and Carr, A, 2017. Arthroscopic subacromial decompression for subacromial shoulder pain (CSAW): a multicentre, pragmatic, parallel group, placebo-controlled, three-group, randomised surgical trial. *Lancet*, 391, pp. 329-338.
[http://dx.doi.org/10.1016/S0140-6736\(17\)32457-1](http://dx.doi.org/10.1016/S0140-6736(17)32457-1)

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1. What are the aims of the study? **(2 marks)**

The aims of the study are:

- To investigate the effect of surgery on the Oxford Shoulder Score by comparing shoulder surgery with and without the essential surgical element (surgical decompression vs arthroscopy only) **(1 mark)**
- To assess the effectiveness of surgical intervention by comparing surgery both decompression and arthroscopy only against no treatment **(1 mark)**

2. What type of study design was used (3 marks)? Provide evidence from the paper to support each point (3 marks). **(6 marks total)**

Design feature - any 3 marks from:

- Multicentre **(1 mark)**
- Randomised **(1 mark)**
- Parallel group **(1 mark)**
- Placebo-controlled **(1 mark)**

Evidence - any 3 marks from:

- Used 32 hospitals / 51 surgeons **(1 mark)**
- Patients were randomised into three groups **(1 mark)**

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- Each subject was assigned to one of three distinct treatment / intervention groups **(1 mark)**
 - Sham control group **(1 mark)**
3. List two problems with 'sham surgery'. **(2 marks)**
- Recruitment problems as patients may not want to be allocated to a no treatment group **(1 mark)**
 - Could be considered as unethical **(1 mark)**
4. List the three null hypotheses for the study (3 marks) and what questions were the authors asking in each hypothesis (3 marks). **(6 marks total)**
- **Null hypothesis** - There was no statistically or clinically significant difference in Oxford Shoulder Score between surgery (decompression) and arthroscopy only **(1 mark)**
 - **Asking** - This comparison accounts for the placebo effect of surgery and informs whether the surgical element - removal of bone and soft tissue, was necessary **(1 mark)**
 - **Null hypothesis** - There was no statistically or clinically significant difference in Oxford Shoulder Score between surgery (decompression) and no treatment **(1 mark)**
 - **Asking** - This evaluates the benefit of decompression with bone removal, bursa and soft tissue **(1 mark)**
 - **Null hypothesis** - There was no statistically or clinically significant difference in Oxford Shoulder Score between arthroscopy only and no treatment **(1 mark)**
 - **Asking** - This evaluates the benefit of arthroscopy without removing bone, bursa and soft tissue **(1 mark)**
5. This was a superiority trial. What do you understand by this? **(1 mark)**
- Superiority trials are used when comparisons are made to a placebo **(1 mark)**.
6. Comment on the primary outcome measure for the study. **(2 marks)**
- This is patient-centred and is clinically relevant **(1 mark)**

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- This relies on self-reflection and so would be open to subjective opinion **(1 mark)**

7. Comment on the baseline characteristics of the three groups. **(1 mark)**

They were similar and therefore equivalent **(1 mark)**.

8. In Figure 2, which lines represent arthroscopy only, decompression and no treatment? **(3 marks)**

- Red line with red square = arthroscopy only **(1 mark)**
- Blue line with blue diamond = decompression **(1 mark)**
- Green line with green circle = no treatment **(1 mark)**

9. Based on Table 2 and the intention to treat data, interpret the mean Oxford Shoulder Scores at 6 months. **(4 marks)**

- The mean Oxford Shoulder Scores did not differ between the two surgical groups at 6 months **(1 mark)**

(1 mark for data):

- Decompression mean 32.7 points [SD 11.6]
- Arthroscopy mean 34.2 points [9.2]
- Mean difference -1.3 points (95% CI -3.9 to 1.3, $p=0.3141$)
- Both surgical groups showed a statistically significant ($p<0.05$) increase in the mean Oxford Shoulder Score compared with no treatment (mean 29.4 points [SD 11.9])

(2 marks for data):

- Decompression was higher by 2.8 points [95% CI 0.5-5.2], $p=0.0186$
- Arthroscopy was higher by 4.2 points [1.8-6.6], $p=0.0014$

10. Based on the sample size calculation, which of these differences would be clinically significant? Justify your answer. **(2 marks)**

1 mark each - any 2 marks from:

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- In the sample size the clinical difference was set at a difference of 4.5 points
- The difference in mean Oxford Shoulder Score between the two surgical groups at 6 months would not be clinically significant as the upper limit of the 95% CI for the difference was less than 4.5 points
- The difference in mean Oxford Shoulder Score between both surgical groups and no treatment at 6 months would be clinically significant as the upper limit of the 95% CI for the difference was greater than 4.5 points in both comparisons

11. List three strengths of this study. **(3 marks)**

1 mark each - any 3 marks from:

- Randomised placebo-controlled design with three groups (including both placebo and no-treatment arms) **(1 mark)**
- Multiple follow-up assessments **(1 mark)**
- Use of valid patient-reported outcome measures **(1 mark)**
- Wide range of sites and surgeons increased the generalisability of the results **(1 mark)**
- Blinding of the assessors and patients to the specific surgical intervention was also a strength with regard to the comparison of the decompression and arthroscopy only groups **(1 mark)**

12. List three limitations of this study. **(3 marks)**

Any three marks from:

- Non-compliance to treatment allocation. Some patients assigned to surgery improved while waiting and did not proceed with surgery, whereas others assigned to no treatment chose to undergo decompression surgery **(1 mark)**
- Patients in both surgical groups received postoperative physiotherapy advice on mobilisation and exercises. This could have affected outcome, and therefore we remain unsure of the mechanism for the benefit gained in the surgical groups **(1 mark)**
- Study also did not address long-term recurrence of any pain and problems beyond 1 year **(1 mark)**

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- Did not adjust for multiple comparisons as per the protocol and the statistical analysis plan given the nature of three groups (**1 mark**)
- A further limitation was that patients could not be masked to treatment in the no treatment group, and they therefore might have perceived their treatment to be inferior to surgery. This perception could have adversely affected the outcome (nocebo effect) (**1 mark**)

Total Marks = 35 marks