Reviewer's report

Title: Percutaneous balloon kyphoplasty for the vertebral compression fractures

Version: 1 Date: 30 May 2013

Reviewer: Georg Osterhoff

Reviewer's report:

General comments
This is a study on the effectiveness and safety of balloon kyphoplasty (BKP) in patients with vertebral compression fractures (VCF). During the last years similar and better designed studies have been published resulting in quite similar conclusions. In addition, I have concerns on several aspects in the methods and results sections and thus the authors' specific conclusions.

However, if these concerns were clarified, the submitted manuscript might serve to confirm existing knowledge on the potential benefits of BKP.
Thus, the authors are advised to rewrite the whole article - especially the Methods and Results section - and I therefore suggest major revision before publication in BMC Surgery can be considered.

Specific comments
Numbering the lines would help making these comments.
Throughout the manuscript, I suggest spelling out numbers from one two twelve when stated in a sentence (except decimals and percentages); e.g. “three leakages” instead of “3 leakages”.
I am not sure if a difference of .01 degrees of kyphotic correction or of .01 in scores like the VAS or ODI are clinically relevant. Round all numbers in the manuscript to maximum one decimal place (except p-values). Omit “0” in numbers like “0.05” (-> “.05”).

1. Title:
I suggest “Percutaneous balloon kyphoplasty for the treatment of vertebral compression fractures”.

2. Abstract:
The Abstract of the manuscript should not exceed 350 words.
Adapt the abstract according to the suggestions made in the sections below.

3. Background:
page 5, line 7, “which can be attributed to pseudarthrosis…kyphoscoliosis”: Please provide reference.
page 5, line 14, “…bed rest, external fixation, and/or…”: Please define “external
fixation”. By corset?

4. Methods:
The description of patient inclusion/exclusion is imprecise. Was inclusion done consecutively? How many patients were included? How many were excluded? If 187 patients were operated between 2011 and June 2012, how is it possible that 187 patients were analyzed?

How long was the median follow-up (and range)? In Table 1 the authors state that four patients were lost to follow-up; when?

Seventy-nine percent of the patients have a follow-up of less than 12 months! This is a key limitation of the study and is not even mentioned in the discussion.

page 6, line 18: Provide IRB approval reference number.

page 7, line 9: “The study was board”: This was mentioned before (page 6, line 18).

page 8, line 6: “unilaterally”: It is interesting that you achieved such a good kyphotic correction by the use of only one balloon. Did you inflate/deflate the balloon in several positions to gain symmetric angular restoration? As stated in Table 2, three vertebrae were approached bipedically. Please add in the Methods section and explain why you did this in some cases.

page 8, line 13: As stated by the authors in the discussion section, the viscosity of the cement is of great importance. How was viscosity determined or estimated before injection?

page 8, line 17: There is a verb missing in this sentence.

page 8, line 19: The authors use different terms to describe the kyphotic deformation/correction: “kyphosis angle”, “kyphotic angle” or “Cobb angle”. Adhere to one term throughout the manuscript and define precisely how it was measured (e.g. endplate-to-endplate of the fractured vertebrae).

page 9, line 1: How was leakage assessed? By radiographs or by CT scans?

page 9, line 8: How is this possible if some patients were operated in June 2012 (invitation for this review was made in May 2013)?

page 9, line 13: The SF-36 was not mentioned before in the Methods section, no results are given in the Results section…

page 9, line 16: Did you adjust for multiple comparisons?

5. Results

Round all numbers in the manuscript to maximum one decimal (except p-values).

page 10, line 5: Provide precise p-values (<.05 is not sufficient).

page 10, line 5 ff: Use “°” and “%” for all the numbers before and after the “±” (as correctly done in line 4).

page 10, line 5, “to 8.21±0.85 at last follow-up”: Last follow-up would be defined as the last follow-up of an individual patient (and therefore include data of ALL
251 vertebrae in 187 patients minus those lost to follow-up = xxx vertebra in 184 patients). The number “8.21±0.85” given in the text, however is the value given for the “Post-op month 12” in Table 3 (and therefore includes only those vertebrae in the 39 patients with a follow-up of 12 months (Table 1). The same accounts for the value given in the text for “last follow-up” of anterior vertebral height. Please clarify.

page 10, line 6: Fifty-two percent of what? How was 100 % anterior vertebral height defined?

page 10, line 17: Suggest “patients”.

page 11, line 3+4: Suggest “leakages”

Did you have any other peri- and postoperative complications?

Six patients with fractures due to malignancies (Table 1, metastasis 1, MM 5) were included. Did you observe differences in the clinical outcome (ODI/VAS) at 12 months when compared to the osteoporotic patients?

6. Discussion:

I would suggest to less describe what is already known and to focus on specifically discussing the results of this study with the current literature. Restructure the discussion as follows: 1. reiterating the purpose and the major two or three findings of the study. 2. compare and contrast these with available evidence. 3. discuss the limitations of the study (e.g., strengths and weaknesses, etc.). 4. discuss areas for future study and research. 5. give a clinical message.

page 13, line 10: Werner et al (J Bone Joint Surg Am. 2013;95:577-84) reported cement leakage rates of 25 % when assessed by CT scan. How did you assure not to miss a leakage?

page 13, line 11-15: This was not investigated by the submitted study.

7. Conclusion:

page 13, line 18, “less”: less than what?

page 13, line 18, “We conclude that compared with nonsurgical management…”: This conclusion cannot be drawn based on the data provided by the submitted study, there was no control-group.

page 14, line 2, “…in our 12 months follow-up”: I would be very careful with this conclusion as most of the patients had a follow-up of less than 12 months.

page 14, line 2, “The treatment of VCFs with balloon kyphoplasty…”: I totally agree with this conclusion.

8. Figures & Figure legends:

Figure 1-6: The procedure of BKP is well known. I would suggest to omit Figure 1+2, to merge Figure 4-5 and to shorten the Figure legends accordingly. You might provide a Figure that shows the technique of kyphotic angle measurement.

9. Tables:
Tables were commented above. Provide “n” in the columns of Table 3.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests