Author's response to reviews

Title: Does visualisation during urethrocystoscopy provide pain relief? Results of an observational study.

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Author's response to reviews: see over
Dear Editor-in-Chief,

Thanks much for the reviewers and editorial comments. Attached please find a revised version of the manuscript. All changes are marked “bold”.

Please find the detailed point-by-point response to each of the referees and editorial concerns:

Reviewer 1 (Alberto Calori)
- Reviewer 1 accepted the manuscript without any revisions

Reviewer 2 (Filippo Maria M Turri)
- The mentioned actual published manuscript was added and discussed. These newly data are in line with our findings.

Editorial Comments
1. As the study was done to investigate clinical data of patients treated solely at our institution in a scientific intent and data were obtained anonymized concurrently, an approval of the local ethics committee (Ethics Committee, Faculty of Medicine Marburg) was not required.
according to the German Ethics Committees regulations (Source: Raspe H, Hüppe A, Strech D and Taupitz J. Empfehlungen zur Begutachtung klinischer Studien durch Ethik-Kommissionen. Deutscher Ärzte Verlag, Köln 2012). Additionally before starting the study we talked with our Ethics Committee and they confirmed that it was not necessary to obtain patient consent for procedures and analysis of daily clinical routine data.

2. Details about the study were given after the urethrocystoscopy was performed, but before the data was assessed. So the patient's choice of procedure could not be influenced by the fact, that his or her data would later be used in a pain related study. We agree that had patients known beforehand that they participated in a pain related study, the results might be biased, as it might increase their pain awareness. Of course, before assessing the data the patients always had the choice to not participate.

3. All performing urologists were aware of the study design. Still, we don't think they could have knowingly influenced the study outcome by recommending one method in particular, as the study was done in everyday clinical practise, the urologist who obtained informed consent of the patient and gave recommendation, did not know beforehand whether or not he or she would also perform the urethrocystoscopy. Other then the patient's written consent to the procedure, no record of what was discussed beforehand exists. Nevertheless we believe that a certain level of bias was probably introduced when a recommendation was given, as every performing urologist probably recommended the procedure he or she was most familiar with, when asked about his or her opinion. We discuss this interesting point more detailed in the discussion part together with comment 4 (page 9 line 9-13).

4. In similar studies this point has been adressed differently. In our study and the study of Soomro et al. more than one urologist performed the procedure. In the studies done by Patel et al., Zhang et al. and Clements et al. only one urologist performed urethrocystoscopy. We think both approaches could include possible bias. We pointed out this problem and discussed it more detailed in the discussion part together with comment 3 (page 9, line 9-13).

5. More that one nurse assessed the pain score. They were not supervised while collecting the patient's data, but given instructions beforehand about the purpose of the study. Usually the data was collected after the performing urologist left the room. We don't believe they influenced the given response. As professional healthworkers in a university hospital, they are all aware of how important objectivity is in medical research. For the exactly same reasons you already gave, we suggested that the assisting nurse should collect the data, as the nurse might get a more honest response from the patient. A variety of nurses assessed the data. As this study took place in everyday clinical practise, it was necessary that more than one nurse could assess the data. We don't think this biased the outcome. One nurse assessing the data during the whole study might be more likely to influence the outcome due to subjective experiences and observations.

6. Unfortunatly, we did no follow up. Almost all patients who had urethrocystoscopy participated only once in our study. Only a very small number of patients had urethrocystoscopy more than once during our study. So we can not answer your question with our data. We
added the manuscript of Greenstein et al (2014) in our discussion part: they underline the difference on pain level of the first and repeated cystoscopies.

7. We did if the patients had had a urethrocystoscopy before, but we did not assess when or where they had it and whether they were able to watch the procedure on a real time screen. As our study only covered the time span of a year, we had probably only a very small number of patients who had urethrocystoscopy twice during the time we assessed data.

8. We did not evaluate whether patient had had rigid or flexible urethrocystoscopy before.

9. Thank you very much, we have corrected this mistake.

Reviewer 1 had no revisions and reviewer 2 only minor revisions – these were corrected.

The editorial comments were addressed point-by-point: a possible bias in all levels of a cystoscopy (from consent of procedure to procedure itself and postinterventional data assessment) and can not be excluded in all. On the other hand this study deals with prospective data of daily clinical routine and are interesting for daily urologist work.

After addressing all comments we hope, that the manuscript is now acceptable for publication in BMC Urology.

If there are any questions please do not hesitate to contact me.

With best regards
Yours sincerely

(Prof. Dr. A. Hegele)