

## **Author's response to reviews**

**Title:** A randomized, controlled trial of spinal endoscopic adhesiolysis in chronic refractory low back and lower extremity pain

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## **RESPONSE TO EDITORIAL TEAM AT BIOMEDCENTRAL**

**TITLE: A RANDOMIZED, CONTROLLED TRIAL OF SPINAL ENDOSCOPIC ADHESIOLYSIS IN CHRONIC REFRACTORY LOW BACK AND LOWER EXTREMITY PAIN**

Dear Editorial Team:

Thank you for your hard work in providing the comments by Drs. Gabor B. Racz and Gerbrand Groen.

Both the reviewers were exceptionally professional with constructive criticism. The following is our response to the reviewer's reports and comments.

### **REVIEW BY DR. GABOR B. RACZ**

- 1) We appreciate the comments by Dr. Racz. We have cleaned up the manuscript quite a bit as he has suggested.
- 2) Following the advice of Dr. Racz, we have described the levels of epiduroscopy in detail. This should resolve the questions he raised in the paragraph with regards to femoral versus sciatic nerve involvement. Consequently, as suggested, it is spelled out.
- 3) We have mentioned the relevance or lack thereof of epiduroscope with its visual inspection and its diagnostic capability. As described in the text, we are unable to determine any utility as a diagnostic test and we have been unable to assess its role for diagnostic utility.
- 4) We understand the cost of the device is higher than either one-day or three-day percutaneous adhesiolysis. Yet, we have not established any diagnostic utility and we are not convinced that any others have established such utility.

Even though this methodology is more expensive than one-day or three-day percutaneous adhesiolysis, we believe that there is a role for endoscopic adhesiolysis in patients after failure of one-day or three-day percutaneous adhesiolysis and the differences are demonstrated in this manuscript.

- 5) We have removed the vague description about less invasive and ineffective treatment. However, we did add that caudal epidural steroid injection as an ineffective treatment in this particular group of patients.
- 6) The invasiveness as Dr. Racz states is the same in both treatments in this study. However, the invasiveness of a caudal epidural steroid injection is less compared to any type of adhesiolysis when it is performed in a clinical setting.
- 7) The sedation was provided with fentanyl and midazolam. It has been accurately described now.
- 8) The medication administration has been described to be loose by Dr. Racz. Medication issues with regards to medication administration have been addressed. We have described the number of patients in each group receiving different doses.
- 9) We were unable to evaluate 100% increase in the steroid dosage and its effect as we utilized

100% increase only in the patients who had bilateral pain. This was done in control as well as intervention group in all patients with bilateral pain. The details are described in the results section.

Thus, we do not believe that failure group was coming from one of those dosage administrations.

- 10) Pathology was identified based on the clinical symptomatology and radiographic evaluations by epidural fibrosis and stimulation of the nerve roots with pressure with endoscope this has been described in the methodology section.
- 11) The details of the amount of contrast utilized as well as normal sodium chloride solution for irrigation are described.
- 12) We also described the potential complications even though these have not occurred in our practice.
- 13) Thank you for the comments on randomization and outcome measures.
- 14) The adverse affects have been discussed.
- 15) The fluoroscopic time is increased generally. It is one of the disadvantages of this procedure compared to one day or three day adhesiolysis.
- 16) Comments on page 17 have been modified.
- 17) The comments in the conclusion section have been modified.
- 18) This paper as Dr. Racz says could be simply a percutaneous adhesiolysis with a larger bore catheter with similar outcomes. However, inclusion criteria as described, clearly was that the patients have failed one day percutaneous adhesiolysis. We certainly welcome suggestions to compare with larger bore catheters
- 19) Comments about future treatments: Authors have not investigated this. Thus, based on this investigation we will not be able to comment on neuromodulation or other procedures. However a repeat procedure could be performed without any serious complications if appropriate precautions are undertaken. It has been added to the text.
- 20) Failure of percutaneous adhesiolysis has been described now clearly with definitions.
- 21) Thank you Dr. Racz for remaining comments.
- 22) Visualization has not contributed to the diagnostic impression. However, we believe that it has contributed to better adhesiolysis.

## REVIEW BY DR. GERBRAND GROEN

- i. We would like to thank Dr. Groen for general comments and constructive criticism.  
We have also specifically described along with the number of patients receiving the dosages.
- ii. Major compulsory revisions:
  1. We have included the article by Dashfield and also have commented in the text.
  2. Results section: The numbers shown in the results in the flow chart are accurate. We considered the patients unblinded at 6 months for purposes of preliminary report as not unblinded. They were unblinded only by the statistician and the statistician tabulated the results. Consequently none of the investigators, other staff or the patients were aware of the groups. Hence, we believe that this should not have affected the results. Further, the results of 39 patients have already been described in the earlier report for 6 months. The results in both reports are similar. Thus, we believe that it is unnecessary duplication of the efforts will result in multiple additional tables and figures.
- ii. Minor essential revisions
  3. Mentioning of control group, group 1, etc. has been revised to match the recommendation.
  4. Injection volume: We have described clearly now how many patients have received the 12 mg betamethasone or 80 mg methylprednisolone.  
  
All the patients with bilateral pain in both groups received 12 mg of betamethasone or 80 mg of methylprednisolone consequently there were no differences in the control or intervention group.
  5. Exclusion criteria: We showed in the flow chart 20 patients as not meeting inclusion criteria and 59 patients refusing to participate.
  6. Methods/Duration of Pain: The protocol approved by IRB was for pain of at least 6 months. However, none of the patients had pain of less than 2 years even for consideration. Consequently we added as 2 years. However, if Dr. Groen desires, we can change that to at least 6 months.  
  
The mistake in the table has been corrected it should have been years rather than months. We are sorry for this typographical error.
  7. Catheter has been added.  
  
Exclusion criteria have been described similar to the previous report (the reference added).
  8. The sentence changed as per Dr. Groen's comments.
  9. Table 3 had a typographical error that has been corrected. It should have been 10.4 instead of 1.4.

10. Flow chart clarified with further descriptions.

11. Figure 2 corrected.

The number of patients analyzed at each period is shown in Figure 1. Intention to treat analysis was applied. Thus, those numbers are also shown in Figure 1.

#### Discretionary Revisions

12. We have studied such evaluation in the past for one day adhesiolysis however we are not quite sure how to incorporate those results into the present evaluation.