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Ozone Therapy and Lower Back Pain

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We read with interest Bonetti et al's article "Intraforaminal O2-O3 Versus Periradicular Steroidal Infiltrations in Lower Back Pain: Randomized Controlled Study," which appeared in the May issue of the AJNR. 1 We came across this paper as we were searching for the possible beneficial effects of ozone therapy in fibromyalgia, which had been pointed out to us at a recent European meeting. The conclusions from this paper are that oxygen-ozone treatment is highly effective in relieving acute and chronic lower back pain and sciatica and that this treatment can be administered as a first option rather than epidural steroids. The authors support their conclusions with percentages and P values noted in the text as well as in the abstract, but not in the Table. In examining the actual data shown in the Table, we realized that the statistical analyses performed were flawed, given that the outcomes (excellent, good, or poor) are not independent observations. Therefore, the comparisons cannot be limited to those patients in one category with the exclusion of those in the others, but rather have to be performed with the entire data in a classic 2 (treatment type) by 3 (outcome type) format (2 df). The data would then read as noted in Tables 1 (for the intermediate outcomes) and 2 (for the long-term outcomes) that accompany this letter. None of the derived χ^2 values shown in these tables reached 5.991, which would be the required value for a significance of 0.05. The conclusions reached in this paper are, therefore, not supported by the data presented.

In light of the possible implications these data may have in supporting the role of ozone therapy for the treatment of back pain (and other painful musculoskeletal disorders), this clarification is essential.

Table 1: Medium-term follow-up in patients with and without disk disease as a function of treatment type

| | Outcome | | | |
|-------------------------------|-----------|------|------|-----------------------|
| Treatment Group | Excellent | Good | Poor | Total |
| Patients with disk disease | | | | |
| $0_2 - 0_3$ | 67 | 9 | 10 | 86 |
| Steroid | 54 | 14 | 12 | 80 |
| Total | 121 | 23 | 22 | $166 \chi^2 = 2.42$ |
| Patients without disk disease | | | | |
| $0_2 - 0_3$ | 55 | 9 | 6 | 70 |
| Steroid | 49 | 10 | 11 | 70 |
| Total | 104 | 19 | 17 | $140 \ \chi^2 = 1.86$ |

Table 2: Long-term follow-up in patients with and without disk disease as a function of treatment type

| | Outcome | | | | |
|-------------------------------|-----------|------|------|-----------------------|--|
| Treatment Group | Excellent | Good | Poor | Total | |
| Patients with disk disease | | | | | |
| $0_2 - 0_3$ | 64 | 9 | 13 | 86 | |
| Steroid | 46 | 16 | 18 | 80 | |
| Total | 110 | 25 | 31 | $166 \chi^2 = 5.51$ | |
| Patients without disk disease | | | | | |
| $0_2 - 0_3$ | 53 | 11 | 6 | 70 | |
| Steroid | 44 | 11 | 15 | 70 | |
| Total | 97 | 22 | 21 | $140 \ \chi^2 = 4.68$ | |

References

 Bonetti M, Fontana A, Coticelli B, et al. Intraforaminal O₂-O₃ versus periradicular steroidal infiltrations in lower back pain: randomized controlled study. AJNR Am J Neuroradiol 2005;26:996–1000

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Reply:

The point raised by our colleagues highlights a mistake arising from an error in transcribing the published table. The correct figures are listed in the table below:

| | Outcome with Steroids | | | | |
|------------------------------------|-----------------------|-----------|----------|--|--|
| Short-term | Excellent | Good | Poor | | |
| With disk disease ($n = 166$) | 64 (80%) | 9 (11.25) | 7 (8.75) | | |
| Without disk disease ($n = 140$) | 55 (78.5%) | 10 (14.3) | 5 (7.2) | | |

Moreover, the advantage of treatment with oxygen-ozone versus steroid clearly emerges in the long-term outcome of treated patients (for which the figures transcribed were accurate) between the 2 groups "with and without disk disease" reporting excellent and good outcomes compared with those with a relatively poor outcome: O_2 – O_3 137 excellent and good versus 19 poor, whereas steroid yielded 117 excellent and good versus 33 poor. This difference is statistically significant ($\chi^2 = 5.228$, P < .025)—ie, O_2 – O_3 treatment has a significantly better long-term outcome than steroids. When the single results are separated out (excellent, good, poor), the long-term effects of treatment are no longer statistically significant, but the higher success rate of O_2 – O_3 treatment is still apparent despite the lower level of significance at the upper limits (disk disease $\chi^2 = 5.502$ against the 5.99 required for statistical significance; and likewise for no disk disease, $\chi^2 = 4.692$).

In conclusion, we regret the transcription error in the Table and apologize for this unwitting mistake. We are grateful to our colleagues for their attentive reading of our paper, which disclosed the error. We are certain that we have now clarified the true significance of our results in line with the overall findings of our paper.

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Changes of Intra-Aneurysmal Pressure during Coiling

We read with interest the article by Cantón et al¹ in the April 2005 issue of the *AJNR* reporting on intra-aneurysmal pressure changes during HydroCoil embolization.

The authors studied the intra-aneurysmal pressure after using hydrogel-coated coils. The intra-aneurysmal pressure was measured by using a standard pressure microprobe placed in a silicone model of a basilar tip aneurysm subjected to pulsatile flow.

Once hydrogel-coated coils are placed within a liquid substance, they tend to swell, similar to the behavior of polymers in a diaper material. Thus, hydrogel-coils depending on the number of cross-links within the polymer and the amount of coils used will incorporate or replace most of the blood within the aneurysm sac.

In trying to address some important biomechanical aspects with the use of HydroCoils, the authors were interested to study fluid pres-