LOCAL DELIVERY OF STEROIDS TO INNER EAR VIA MEDICAL DEVICE INCAT (THE INNER EAR CATHETER) IN PARTIAL DEAFNESS PATIENTS DURING COCHLEAR IMPLANTATION – PRELIMINARY RESULTS.

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1. Background:

The primary aim was to assess the effectiveness and safety of three different algorithms of using steroids and inner ear catheter (INCAT) Medel® in partial deafness patients who underwent cochlear implantation. The secondary goal was the assessment of the impact of the depth of INCAT on hearing preservation after cochlear implantation.

2. Research design and methods:

There were three algorithms of steroid administration: 1) methylprednisolone 62.5 mg/ml (solution), 3 patients; 2) methylprednisolone 40 mg/ml (suspension), 4 patients; 3) dexamethasone 4 mg/ml (solution), 3 patients. Pure tone audiometry (0.125-8 kHz) was performed preoperatively, 1 and 6 months post-op. Hearing preservation was assessed according to the HEARRING group formula. Impedance measurements were taken at two days, 1 and 6 months after surgery.

Table 1. PICOS classification.

PICOS classification	
P (population)	10 patients (aged between 40 and 70 years, mean age *M* = 53.2; SD = 11.1) were enrolled to this study and underwent a CI surgery with an inner ear catheter INCAT. 5 women and 5 men (implanted ear: 8 right ears and 2 left ears). Patients, who were enrolled to the study, were partially deaf and were qualified to the surgical procedure (cochlear implantation). Patients suffered from severe to profound hearing loss.
I (Investigated condition)	The MED-EL electrode arrays used were as follows: Flex 28–3 ears (30%), Flex 24–3 ears (30%), Flex 26–2 ears (20%) and Flex 20–2 ears (20%). The type of cochlear implant electode arrays depend on the depth of the hearing loss. Steroids delivered via the inner ear catheter INCAT: (1) methylprednisolone 62.5 mg/ml (pharmaceutical form: solution) – 3 patients (30%), (2) methylprednisolone 40 mg/ml (pharmaceutical form: suspension) – 4 patients (40%) and (3) dexamethasone 4 mg/ml (pharmaceutical form: solution) – 3 patients (30%). The volume of solution/suspension were 1 µl in 5 patients (50%) and 1,5 µl in 5 patients (50%). The insertion depth of INCAT was as follows: (1) the second dot (10 mm) – 6 patients (60%), (2) the third dot (13 mm) – 3 patients (30%) and (3) the marker ring (20 mm) – 1 patient (10%). The hearing outcomes: Pre-operative (before cochlear implantation) hearing outcomes (mean hearing thresholds at 11 frequencies: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 and 8000 hz).
C (Comparison condition)	Post-operative (CI activation in one month after operation; 6 months after operation) hearing outcomes (mean hearing thresholds at 11 frequencies: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 and 8000 hz).
O (Outcome)	The result of Hearing Preservation (HP): (1) no measurable hearing (loss of hearing); (2) minimal hearing preservation (minimal HP) 0–25%; (3) partial hearing preservation (partial HP) 26–75%; and (4) complete hearing preservation (complete HP) >75%. According to the hearing preservation (HP) formula: $HP = \left[1 - \left(\frac{(PTApost - PTApre)}{(PTAmax - PTApre)}\right) * 100\right][\%]$ Where: – HP is the percentage of hearing preservation, – *PTApost* is the postoperative pure tone average, – *PTApre* is the preoperative pure tone average, – *PTAmax* is the limit of the audiometer.
S (Study design)	Prospective study with ethics committee consent (KB.IFPS 6/2023)

Table 1. The summary of the study design is presented in Table 1 according to the PICOS classification (P – population, I – investigated condition, C – comparison condition (tests results retrospectively), O – outcome, S – study design).

3. Results:

Patients treated with methylprednisolone 40 mg/ml in suspension showed the best hearing preservation (50% complete and 50% partial preservation) 1 month post-op and later remained the most favorable. The lowest impedance was found in this group both 1 and 6 months post-op. A shorter INCAT insertion depth appeared to be more favorable than a longer one.

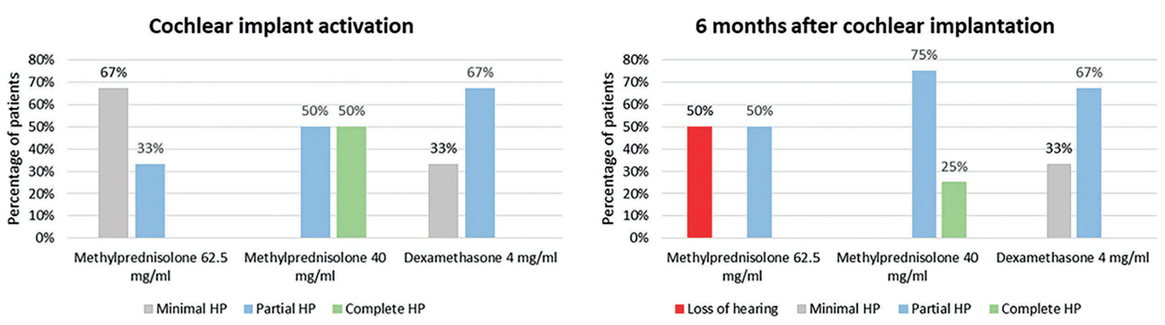


Figure 2. Hearing preservation at the cochlear implant activation (1 month after surgery) and 6 months after surgery according to different algorithms of using steroids and INCAT.

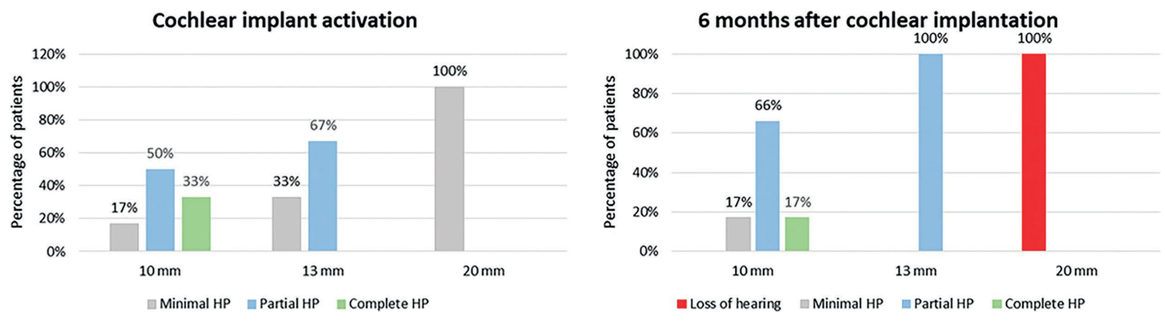


Figure 4. Hearing preservation (HP) at the cochlear implant activation (one month after surgery) according to the depth of the INCAT insertion.

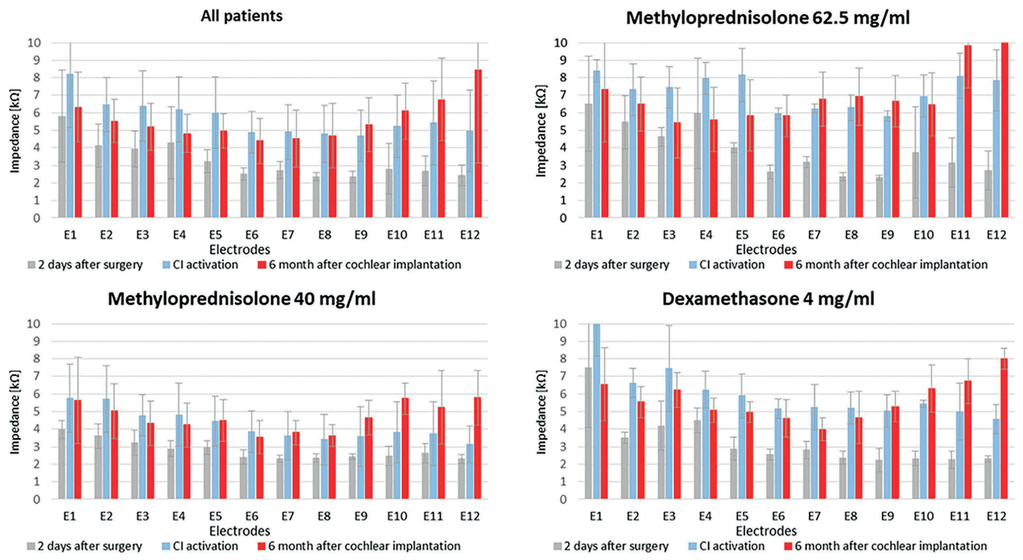


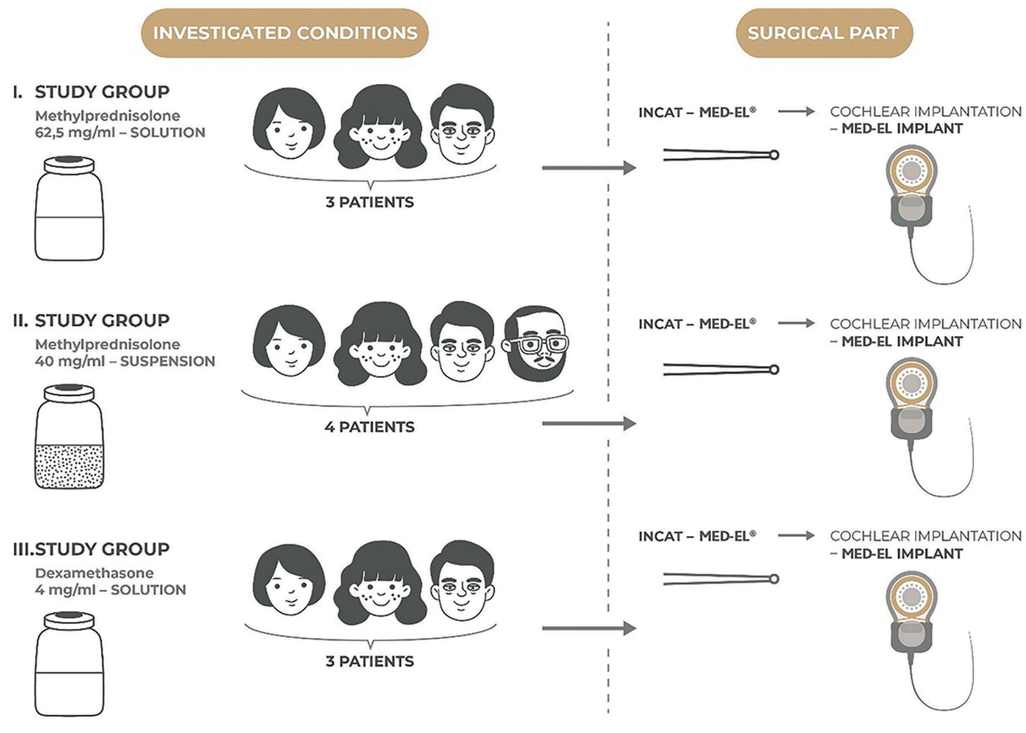
Figure 3. Mean impedance at the implant electrodes 2 days after surgery, at the cochlear implant activation (one month after surgery), and 6 months after cochlear implantation according three different algorithms of using steroids and INCAT.

4. Conclusion:

Our results suggest that patients treated with methylprednisolone 40 mg/ml (suspension) had better hearing outcomes compared to the other two medications.

5. Keywords

Drug delivery; cochlear implantation; partial deafness treatment; steroids.



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