Safety and Efficacy of Carbomethylcellulose Foam in Middle Ear Surgery

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INTRODUCTION

Gelatin sponge (GS, Gelfoam™) has long been used as a middle ear packing material for tympanoplasty. While high gold standard results have been reported with GS, this material has also been shown to induce excessive scarring.1-3 Such scarring has been attributed to inflammatory reactions to the protein content of the gelatin sponge which may stimulate fibroblasts to produce excessive collagen.1-3 Gelatin sponge (GS) has been shown to reduce adhesions and improve hearing results.4-6 Gelatin sponge in its current form has, however, been reported to result in excessive scarring and mucosal necrosis.4-6

Carbomethylcellulose (CMC) preparations have been reported as effective means of reducing adherence and controlling bleeding in other surgical areas, such as the pancreatic tumors.7-9 CMC has been used as an alternative to GS. However, the otologic safety of CMC latex has yet to be established. The aim of this study was to examine possible toxicity resulting from use of CMC foam in the middle ear.

MATERIALS AND METHODS

Fifty-seven animals were used in this study to evaluate the equivalency in healing, hemostasis, and lack of ototoxicity between CMC, HA, and GS. Animals were randomly and evenly assigned to study groups (19 per group). Both ears on each animal were treated. Ears were randomly assigned to either surgery or sham surgery (uninjured ear). Uninjured ear served as a negative control testing to rule out bleeding in other surgical areas, such as the paranasal sinuses.11-14 CMC has been used "off-label" in otologic surgery as an alternative to GS. However, the otologic safety of CMC latex has yet to be established.

Power analysis was performed by biostatistician using a primary outcome measure of hearing loss in study subjects relative to controls. Nineteen animals (19 animals per group) were performed for a power of 80% to detect a 10 dB difference (0.80 power) between control and non-CMC treated ears. For statistical analysis, the Cochran-Armitage trend test was used. Contingency data (deaths, postoperative bleeding, TM perforations and middle ear scarring per group) were analyzed using Chi-Square. A statistical value of p < 0.05 was considered significant. All statistical tests were performed using StatView software (v.5.0 88 Macintosh, SPS, USA). Power analysis was performed by biostatistician using a primary outcome measure of hearing loss in study subjects relative to controls. Nineteen animals (19 animals per group) were used to detect a 10 dB difference (0.80 power) between control and non-CMC treated ears. For statistical analysis, the Cochran-Armitage trend test was used. Contingency data (deaths, postoperative bleeding, TM perforations and middle ear scarring per group) were analyzed using Chi-Square. A statistical value of p < 0.05 was considered significant. All statistical tests were performed using StatView software (v.5.0 88 Macintosh, SPS, USA).

RESULTS

CONCLUSIONS

REFERENCE