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ORIGINAL ARTICLE

Use of pyrolytic carbon coated beads (Durasphere) to treat glottic failure: an experimental study in dogs

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Summary

There is no ideal tissue or substance to be injected in the vocal folds. The objective of the present study was to assess the use of Durasphere in canine vocal fold injection. **Materials and Methods:** in six adult dogs we injected 0.3 mL of Durasphere in the middle third of the thyroarytenoid muscle and 0.3 mL of saline solution in the contralateral vocal fold. The animals were slaughtered after seven days (three dogs) and after 90 days (three dogs). We analyzed the inflammatory process in the vocal fold and in the lamina propria of the vocal folds. **Results:** in the vocal muscle which received Durasphere there was a significantly more intense inflammation when compared to the control muscle - there was a moderate lymphomodular infiltrate after seven days and mild after 90 days. We did not observe foreign bodies nor granulomas. On the lamina propria there was a mild inflammatory process in the two groups, without difference between them. **Conclusion:** this is a substance of proven biocompatibility in humans, with preliminary and unprecedented results and its injection in canine vocal folds caused a moderate inflammatory process after seven days and mild after 90 days, without foreign bodies or granuloma formation.

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INTRODUCTION

Normal laryngeal functioning requires the vocal folds to come close to each other for phonation and protection of the lower airways. When this reunion fails because of paralysis, atrophy or vocal fold fibrosis, glottal insufficiency ensues[1,2,3]. Patients unable to properly close their glottis can suffer of weak and blowy voice and chronic aspiration[3].

Vocal fold injection is the technique used to correct this problem. The most commonly used substances to push the vocal folds medially are: Teflon, gelfoam, autogenous fat, collagen and autologous fascia[1,4,5].

There is no ideal tissue universally accepted to inject in the vocal fold, and each material has its pros and cons. One new substance, Durasphere (Carbon Medical Technologies, St. Paul, Minnesota), made of pyrolithic carbon particles, suspended in aqueous gel[6] was approved by the FDA (Food and Drug Administration) to treat urinary incontinence. Its function is to promote a closure (bulging) when injected in the submucosa of the urethra near the bladder neck, thus reestablishing bladder competence.

The ideal injectable substance must be biocompatible, durable, non-migratory, little immunogenic, of easy injection and which does not alter the viscoelastic properties of the vocal fold[7]. Considering that Durasphere has potential advantages which can be ideal for vocal fold injection, the goal of the present study was to assess the use of Durasphere as a substance to inject in canine vocal folds to treat glottic insufficiency.

MATERIALS AND METHODS

This study was approved by the Ethics Committee for Research Project Analysis - CAPPesq of the Clinical Board of the University of São Paulo Medical School Hospital (protocol # 353/04).

In this study we used adult dogs, of both genders, from the research animal's center of the Medical School of the University of São Paulo, without a defined race and mean weight of 10 kg.

Durasphere (Carbon Medical Technologies, St. Paul, Minnesota) is made of globules coated by pyrolithic carbon suspended in aqueous gel at 2.8% glucan (Figure 1). The particles have sizes which vary between 251 and 300µm.

With the animal in supine position and previously sedated, we carried out a suspension laryngoscopy to expose the animal's glottis. Under light microscopy we injected 0.3mL of Durasphere in the middle third of the right vocal fold, lateral to the vocal process, at about 3mm of depth in the thyroarytenoid muscle, using a 19 gauge needle. The left vocal fold was used as control, and was injected with 0.3mL of 0.9% saline solution in the same site compared to the other fold.

Figure 1. Durasphere in a 1mL syringe.

The animals were slaughtered after 7 days (3 dogs) and 90 days (3 dogs) and submitted to total laryngectomy with dissection of all the structures adjacent to the larynx. We separated the two vocal folds and obtained a five millimeters thick fragment from the middle third of the intermembranous portion of each vocal fold, involving epithelium, lamina propria and vocal muscle. Durasphere - appeared as a well outlined mass of pasty consistency - was carefully removed from the vocal fold in order to facilitate the paraffin bloc cutting, because the results from the prior pilot study with five dogs showed that after paraffin impregnation, Durasphere became very hard, making it difficult to cut the paraffin with the microtome, and this caused muscle tissue laceration, impairing histological evaluation.

The vocal folds were fixed in 10% formaldehyde, dehydrated in 95% ethylic alcohol, cleared with xylol, impregnated by paraffin melted in a 60 degree oven and after that they were cut with the microtome at a 5um thickness.

The slides were dyed with hematoxylin eosin. We analyzed the quantity and type of local inflammatory infiltrate in the vocal muscle and the lamina propria of both vocal folds, for that we used a quantitative and qualitative method.

The inflammatory process was qualitatively graded in mild, moderate or severe, based in the infiltrate intensity. We also noticed foreign body reaction and granuloma formation.

For the quantitative analysis in order to assess the quantity of the inflammatory reaction we chose 10 visual fields at random from the vocal muscle slide and 10 of the lamina propria with optical magnification of 400 times, on top of which we placed a squared grid with 10 vertical and 10 horizontal lines, making up a total of 100 points of intersection. The points were counted in two groups: coinciding points which had inflammatory cells and inclusion points corresponding to the rest of the points. The inflammatory