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Randomized control trials

Endoscopic gastrostomy replacement tubes: Long-term randomized trial with five silicone commercial models

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SUMMARY

Trial design: No analysis of the long-term performance of percutaneous endoscopic gastrostomy (PEG) replacement tubes was identified. A randomized partially blinded trial was designed hypothesizing that clinically relevant limitations of the tubes would be identified.
Methods: Patients ($N = 100$, age 58.3 ± 20.7 years, 42.0% males, time with PEG 27.0 ± 22.5 months) were randomized in five parallel intervention groups, each with a tested device (Silmag®, Bard®, Freka®, Kangaroo® and Wilson Cook®). Eligibility criteria included age 18–90 years, males and females, on home enteral nutrition, and the setting was a large academic hospital. Patients were allocated according to a random numbers list, and independent professionals were responsible for data collection. Primary outcome was tube longevity, calculated by Kaplan–Meier curves and Cox regression analysis. A sample of 18 was calculated based on a 10% effect size and 80% power.
Results: Twenty patients were randomized in each group and all were analyzed. There was no morbidity and mortality, however tube dysfunction was common with all models. Fastener sliding occurred in 57.0% and balloon rupture in 32.0%, along with other mishaps. Best tube longevity corresponded to the Wilson Cook model (158.0 ± 10.0 days, $P < 0.05$), mostly on account of diminished balloon ruptures.
Conclusions: PEG replacement was safe however relatively frequent and affecting longevity, therefore longer-lasting tubes are needed. Specific attention should be given to cap, feeding line, external clamp, tube fastener; tube length, and notably balloon performance, which may be disappointing. Trial NCT01698827, CNPq Investigator Grant 302915/2011-7.

1. Introduction

Percutaneous endoscopic gastrostomy (PEG) is the most widely utilized feeding gastrostomy technique, and the modality of choice for digestive access during long-term enteral nutrition.

In Germany some time ago[1] it was estimated that 140 000 PEGs are implanted yearly. In the light of the population of Germany (~80 million), that of Western Europe (~340 million) and of the USA-Canada (another 340 million), one would calculate a consumption of one million devices/year for these two regions, and more for the entire world.

In the USA Grant et al. anticipated that 10% of nursing home residents are submitted to PEGs. For a total of 1.5 million residents, that would represent 150 000 devices, which demand periodical changes.[2,3] Given the fact that just a minority of sick elderly people are in nursing homes, and that the younger population may also need PEGs, a substantially higher number could be projected. In this sense, the hypothesis of yearly worldwide procedures in the range of one million or more doesn't look far-fetched.

Not all tubes need replacement as transition to oral alimentation and recovery occur in some circumstances, whereas complications or death could determine premature discontinuation of enteral nutritional support in others. Nevertheless as many as half of the tubes are changed in the first 180 days[4] and common substitutions along the PEG life are the rule, routinely or on account of tube dysfunction or dislodgement,[5] thus representing a significant clinical and financial burden.

Multiple models of replacement tubes are available in the market, and although other materials may be preferred, most

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modern devices are made of silicone.[6–9] Still design, convenience of use and especially durability could vary and comparative studies could not be found. In a prospective randomized trial, five commercial silicone products were tested, aiming to assess tube longevity in the outpatient setting. To the best of our knowledge, this is the first such protocol in the literature.

2. Methods

2.1. Trial design

This was a single-center, partially blinded multi-arm parallel randomized interventional cohort trial, registration number NCT01698827, conducted during two years (September/2010 till September/2012), and targeting stable patients with PEG. Twenty procedures were allocated to each arm (total of 100). Partial crossover was permitted, each tube introduction with documentation up to six months being considered an independent observation. Those undergoing subsequent changes could thus be investigated more than once. The setting was the Endoscopy Service of a large public academic hospital (Hospital das Clinicas, Sao Paulo University Medical School, Sao Paulo, Brazil).

2.1.1. Selection, randomization and concealment techniques

Patients and family caregivers already instructed and trained by the hospital team, fulfilling criteria of inclusion and exclusion, were consecutively informed about the study and invited to participate. All of them agreed, and after signing the informed consent they were randomized according to the protocol.

Endoscopists handled tube replacement in accordance with such numbers and were aware of the commercial brand, however both patients and the resident in charge of subsequent data collection and analysis were blinded regarding such information. Subjects managed by professional home care organizations or institutionalized in long-term facilities were not focused in this experience.

2.1.1.1. Criteria of inclusion. Males or females, age 18–90 years, undergoing long-term enteral nutritional support, and handled by silicone tube replacement.

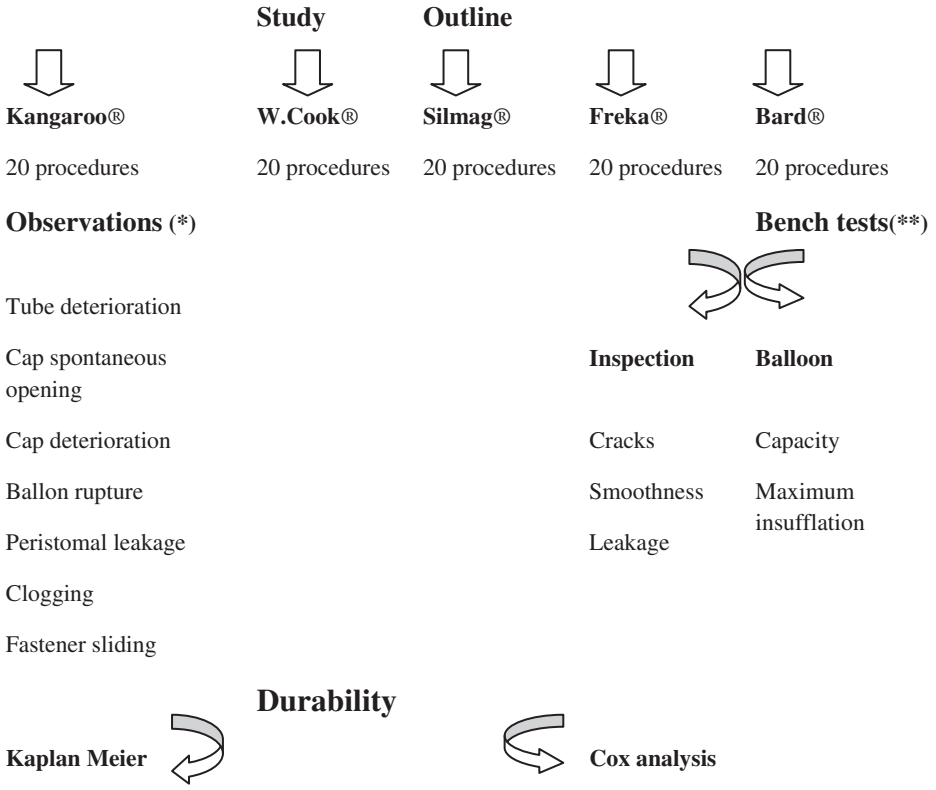
2.1.1.2. Criteria of exclusion. Critical disease, terminal patients, hospital admission, severe disability or technical problems preventing return to scheduled visits, refusal to participate in the protocol.

2.2. Experimental procedures

The hypothesis was that clinically relevant limitations in the tested products would be identified. Primary end-point was tube longevity (calculated dwelling time). This was an eminently clinical investigation however physical complementation was deemed useful. In this sense, unidentified samples of each tube were sent to the laboratory of an independent industry of surgical material (Faga Medical, Bauru, SP, Brazil), for expert assessment of manufacturing defects and balloon performance.

As depicted in Table 1, the investigation encompassed three goals: clinical observations, bench tests including professional inspection and balloon analysis, and as the main end-point, statistical durability studies (Table 1).

Table 1
General protocol design.



(*) Executed in the entire population during scheduled visits (30, 90,180 days)

(**) Conducted in random new samples, which were subsequently discarded