

Prospective pilot study of Floseal® for the treatment of anterior epistaxis in patients with hereditary hemorrhagic telangiectasia (HHT) – Protocol and Statistical Analysis

NCT02638012

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Patients afflicted with hereditary hemorrhagic telangiectasia (HHT) can suffer from frequent and heavy epistaxis, often requiring hospitalization for transfusions and surgical or endovascular procedures. As HHT patients represent a distinct group of individuals who are at increased risk of epistaxis, which has significant negative impact on QoL, evaluation within this specific group was warranted. Herein, we performed a pilot prospective clinical trial evaluating the efficacy of Floseal® in managing acute epistaxis in HHT patients.

Methods

This multi-centered prospective clinical trial was registered with ClinicalTrials.gov (NCT02638012). Research ethics approval was received from both St. Michael's Hospital and The Ottawa Hospital.

Study population

We aimed to recruit 10 patients, which is the sample size that is deemed appropriate for pilot studies. Patients age 18 and above with a documented diagnosis of HHT, and who were experiencing active anterior epistaxis were approached to voluntarily participate in this study. Patients were recruited after the Otolaryngology –Head and Neck Surgery service was consulted, either through the Emergency Department, or from another in-patient service. Patients were excluded if they i) had a known sensitivity to Floseal®, ii) had a known sensitivity to the topical medications administered as part of the evaluation and treatment of epistaxis (lidocaine, xylometazoline hydrochloride) or iii) were pregnant and/or breast feeding (the safety of Floseal® has not been established in pregnant women).

Floseal® treatment

The nasal cavity was suctioned, and the bleeding was visualized with anterior rhinoscopy. A total of 5 mL of Floseal® (one standard preparation) was applied under direct visualization into the affected nasal cavity using the provided application catheter by a senior study investigator (JML or SK). Anterior nasal pressure was then applied for 5 min, and the nasal cavity was then reinspected 15 min after the initial application. In the event that bleeding was not controlled, an additional Floseal® application was to be applied. With failure to control bleeding with 2 applications of Floseal® the protocol was to remove gel and clots with suction, and the patient was to be treated with a standard packing treatment (absorbable or non-absorbable) as standard of care.

Outcome measures

A patient-reported epistaxis questionnaire was administered as part of the study, and included the Epistaxis Severity

Score (ESS). The survey is attached as part of Additional file 1. Modification to the ESS questionnaire included changes with regards to the timing (1 month, as compared to 3 months in the original ESS questionnaire). The patient-reported questionnaire was administered to all patients at the time of the Floseal® application (baseline), and at 1 month following treatment. Patients were also asked to report pain associated with application of Floseal®, rated on a visual-analogue scale from 0 to 10, with 0 being “no pain”, and 10 being “worst pain in your life”.

The primary outcome measures were achievement of hemostasis and changes in the ESS score between baseline and one-month follow up. Secondary outcome measures assessed subjective changes in epistaxis symptoms between baseline and follow up. Additionally, patients were reassessed clinically at 1 month follow up, capturing changes in telangiectasias, crusting, scarring, and active bleeding sites in the nasal cavity. Both sides of the nose were scored separately in each of these domains from 0 to 10, with 0 being “none” and 10 being “severe”. Clinical assessments were only performed by senior study investigators (JML and SK). The clinical assessment form is included as part of Additional file.

Statistical analysis

Descriptive statistics were used to summarize the frequency and percentage of categorical variables. Continuous variables were reported as mean and standard deviation. Paired t-test was performed to compare baseline and one month follow up differences in ESS, frequency of nose bleeds, and severity of nose bleeds. All statistical analyses were performed using Prism (v.7, GraphPad, USA), with significance set to $\alpha = 0.05$.