

The Use Of Foley Catheters In Epistaxis. A Question Of Informed Consent

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Summary

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Background The Medicines and Health care products Regulatory Agency stated in 2003 that doctors should endeavor to avoid using products in treatments not covered by their product license. Foley catheters are commonly used in the management of epistaxis although their product license does not cover this.

Aims : To study the extent of the use of these catheters and the knowledge that otolaryngologists had of their legal status.

Method : By undertaking a questionnaire survey of some Otolaryngologists in Baghdad

Results : Most members appear to use Foley catheters in the management of epistaxis; however most of them are not aware that the product is not licensed for this purpose. Because of this lack of knowledge, only few obtain verbal consent for treatment with this device and none of the surveyed members obtain written consent from patients.

Conclusion :In the era of increasing litigation, documentation of informed consent could be considered mandatory to protect us from possible legal action, and this needs to be known by all practicing Otolaryngologists.

Keywords : Informed consent; Epistaxis; Foley catheters.

Introduction:

Epistaxis is one of the commonest emergencies presenting to the Otolaryngology department.

Many effective treatment options are available. If bleeding is from a site in the anterior part of the nose it may resolve spontaneously with no treatment or be treated without difficulty; however, bleeding from the posterior part of the nose may require more interventional treatment including the use of balloon devices.

Many such devices are licensed for the treatment of epistaxis, including the Brighton balloon (Eschmann) and the Epistal nasal catheter (Xomed). Foley catheters with or without anterior ribbon packing are also used, although they are not licensed for this treatment.⁽¹⁾

The 1st use of a Foley catheter in nasal hemorrhage to treat a post-adenoidectomy bleed was reported in 1956.⁽²⁾

Over the decades since then, Foley catheters have been used in the management of posterior epistaxis with little questioning of the license.⁽¹⁾

Their widespread use is documented and they provide a well known, easy, cheap and readily available way to arrest hemorrhage.⁽³⁾

The Medicines and Health care products Regulatory Agency stated recently that health care workers could face legal consequences if

complications arise when devices are used outside of the terms of their license (Foley catheter is used in the treatment of urinary retention and other problems of urinary system in addition to its use as a parameter for monitoring the urine output in any critically cared patient); obviously this includes using Foley catheters in the treatment of epistaxis.⁽⁴⁾

When devices are used within terms of an existing license, and complications arise as a result of the product being defective, the liability rests with the producer.

However, where a device is used outside of the terms of its product license (or is unlicensed altogether) the supplier (i.e. the doctor or their employer) may be liable for a defective product.

A Pub Med search using the terms 'Foley catheter and posterior epistaxis' was undertaken to look at reported complications of the Foley catheter used as a balloon device to arrest epistaxis.

Complications included localized pressure necrosis, sinusitis, secretory otitis media, failure of the Foley catheter to deflate, airway obstruction and tendency to rupture when in contact with paraffin gauze.^(5, 7) Unfortunately, the rates for each complication are unknown.

This study analyzes the use of Foley catheter amongst some Iraqi Otolaryngologists and their awareness of its complications, license state and the current advice on consent.

Materials and Methods:

A survey of fifty lists questionnaire were sent to most of the consultants and registrars working at the three major centers of Otolaryngology in Baghdad (Medical City 10 specialists , Al-Yarmouk

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Teaching Hospital 5 specialists, and the University Hospital of Al-Kadhmia 5 specialists) in addition to some ENT surgeons from the different hospitals in Baghdad (30 specialists).

The Questions included:-

1. Have you ever used Foley catheters for the treatment of posterior epistaxis?
2. Do you use Foley catheters as a first line treatment for posterior epistaxis?
3. How is the anterior end of the Foley catheter supported?
4. Which other products do you use as a first line treatment to treat epistaxis?
5. Are you aware that Foley catheters are not licensed for treatment of epistaxis?
6. Have you ever had an adverse incident or are you aware of any adverse incidents with the use of Foley catheters?
7. Do you obtain consent from patients prior to the insertion of Foley catheters?
8. Are you aware of current advice on consent?
9. Is the consent documented in the patient's notes?

Results

Fifty list questionnaires were obtained. Almost all of the questionnaired doctors used Foley catheters for the management of epistaxis and seven members only (14%) used Foley catheters as a first line treatment for posterior epistaxis.

Of the consultants and specialists who were using Foley catheters as a first line and second line treatment for posterior epistaxis, only 15 (30%) of them were aware that this product is only licensed for use in the urinary tract and only 12 (24%) of them were aware of any adverse incidents (Table 1).

In the group that used Foley catheters as a second line treatment for posterior epistaxis, 90% use Vaseline or paraffin/BIPP packing, 30% use cautery (electrical or chemical) method (some using more than one product as first line treatments).

All the complications associated with Foley catheters that members experienced have been documented in the literature. ^(5,7)

It was also noted that the way in which the anterior end of the Foley catheter was supported varied widely, as it does in the literature. ^(8,9)

When members were asked if they gained consent from patients prior to insertion of the Foley catheter, the results showed that only 10 members (20%) obtained a verbal consent only and none of them obtained written consent. Only around third were aware of current advice on consent.

It is important to mention that most of the postgraduate trainees do practice a similar attitude when managing a moderate – severe epistaxis during their postgraduate training although they were not involved directly in this survey. This is based on their verbal opinion and the background of knowledge of their training skills in different teaching hospitals in Baghdad.

Table1: Foley catheter: awareness of license state and adverse incidents and obtaining consent.

Hospital	Members Surveyed	Foley catheter as 1 st line	Foley catheter as 2 nd line	Awareness of license	Awareness of adverse incidents	Verbal consent obtained	Written consent obtained	Aware of current advice
Aljerahat	10	1	9	4	3	3	Nil	5
Alyarmouk	5	1	4	2	2	1	Nil	2
University Hospital	5	1	4	2	2	1	Nil	2
Others	30	4	26	7	5	5	Nil	6
Total	50 (100%)	7 (14%)	43 (86%)	15 (30%)	12 (24%)	10 (20%)	Nil (0%)	15 (30%)

Discussion:

Epistaxis is an Otolaryngological emergency, moderate - severe epistaxis is usually treated in the hospital. Patient first attend the junior and the postgraduate trainee doctors, who may use Foley catheter as an urgent treatment, probably due to its easy application and good results in difficult circumstances.

This is usually done without neither obtaining informed consent from the patient nor asking the consultants for this intervention. However, the questionnaire submitted to the specialists were

referring the whole period of their Otolaryngological practice including the pre. and post specialty period.

Almost all of the Otolaryngologists appear to use Foley catheters in the management of epistaxis, even though this product is only licensed for use in the urinary tract.

In an era of increasing litigation in medical practice, documentation and informed consent are mandatory and, as can be seen from these results, as

a profession we are leaving ourselves exposed to potential litigation.

Should a claim for clinical negligence be pursued, in order for the doctor to defend his successfully, it would be necessary to demonstrate that the doctor's actions had been in accordance with a reasonable body of medical opinion.

This might include obtaining favorable expert opinion, or demonstration that there was sufficient evidence supporting use of the catheter. Claims or complaints could be focused around the issue of informed consent regarding the use of Foley catheters outside of their license.⁽¹⁰⁾

Doctors would be expected to ensure that patients have been given sufficient information for them to give fully informed express consent, and that their decision was voluntary.

In its guidance on 'prescribing medicines' the general medical council states "when prescribing a medicine for use outside the terms of its license you must:

1. Be satisfied that it would better serve the patient's needs than an appropriately licensed alternative;
2. Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy. The manufacturer's information may be of limited help in which case the necessary information must be sought from other sources;
3. Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring and any follow-up treatment, or arrange for another doctor to do so;
4. Make a clear, accurate and legible record of all medicines prescribed. And, where you are not following common practice, your reasons for prescribing the medicine.

It would be advisable to document that the patient has been informed of the following:

- 1) The device was being used outside of its license.
- 2) The known side effects of the device or treatment used.

- 3) The risk/benefit of all the available alternatives.

Our results are therefore of potential concern, as few physicians are documenting consent and this could lead to litigation. There are other examples where products are used outside of their license; for example, using a Foley catheter to act as a feeding tube via a tracheoesophageal fistula after a total laryngectomy. These cases could potentially also be affected by this advice.

All patients are then informed that the use of a Foley catheter for the management of epistaxis is not licensed but that having tried other methods we believe that this form of treatment is the best option as usually management needs to be speedy, and then, once the clinical situation is more controlled, formal written consent is obtained on specific consent forms that are placed in the notes.

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