

Tolerability and Safety Profile of Povidone Iodine in Pre-Operative Skin and Eye Disinfection Prior to Intraocular Surgery

Theocharis Papanikolaou^{1*}, Tahir Islam² and Adnan Hashim³, George Mariatos⁴

¹Addenbrooke's Teaching Hospital, Cambridge, United Kingdom

²Hull & East Yorkshire Eye Hospital, Hull, United Kingdom

³Rotherham General Hospital, Rotherham, United Kingdom

⁴Barnsley General Hospital, Barnsley, United Kingdom

Abstract

Purpose: To audit the safety profile of Povidone Iodine for skin and eye disinfection prior to ocular surgery.

Methods: The skin of 132 patients undergoing cataract surgery was prepared with Povidone Iodine 10% (Videne® 10%). This was then diluted 50:50 with normal saline and a few drops were instilled in the conjunctival sacs of the eyes to be operated on. The patients were asked to report any discomfort while disinfecting the skin and the conjunctiva and the sensation was graded from 0 (no discomfort) to 5 (most severe discomfort).

The corneal clarity was then assessed throughout surgery. Corneal haziness was graded from 0 (none) to 5 (very marked). The comparison standard used was the results of a survey reported by Trinavarat et al. "Reduction of Endophthalmitis Rate after Cataract Surgery with Preoperative 5% Povidone-Iodine. *Dermatology* 2006; 212 (suppl 1): 35-40"

Results: 116 patients (87.9%) reported no discomfort with application of Povidone Iodine 10% to skin and no discomfort with application of Povidone Iodine 5% to the eye. There was no corneal haziness resulting from the application of Povidone Iodine. Thirteen patients (10%) experienced very mild (+1) and brief conjunctival discomfort. Two patients (1.5%) experienced a very mild (+1) skin irritation. One patient (0.75%) experienced a very mild conjunctival (+1) and a very mild (+1) skin irritation. Five patients (3.7%) had preoperative superficial punctate keratitis due to poor tear film which had resulted in very mild corneal haziness. This did not change with the application of Povidone Iodine. There were no pre-operative, per-operative or post-operative complications.

Conclusions: Povidone Iodine (Videne®) is safe for preoperative disinfection in ocular surgery.

Keywords: Videne®; Betadine®; Povidone; Iodine; Eye; Surgery

Introduction

It is standard practice to use Povidone Iodine 10% diluted 50:50 for pre-operative disinfection in ocular surgery. Until recently there have been two preparations of Povidone Iodine in the market, Betadine® and Videne®, both used in ocular surgery, some units using one and some units using the other.

The discontinuation by the manufacturer of Betadine® has caused some controversy with regards to the safety of Videne® in ocular surgery, in the units that were not using it.

We audited the safety and tolerability profile of Povidone Iodine (Videne®) in 132 eyes prepared pre-operatively with Videne®, which is the standard practice in our unit, before phacoemulsification surgery.

Materials and Methods

The sample consisted of one hundred and thirty two patients who underwent cataract surgery in our department.

Inclusion criteria were: Patients scheduled to undergo cataract surgery.

Exclusion criteria were: Any ocular pathology that could impair corneal clarity or any cause of diminished corneal sensation or both.

The skin was disinfected with Videne® 10%. Then Videne® was diluted 50:50 with normal saline to achieve a concentration of 5% and a few drops were instilled in the conjunctival sac.

A questionnaire enquiring about the presence of any ocular symptoms such as pain, discomfort and burning sensation was filled

in while the skin and the conjunctival sac were disinfected by the surgeon. The patients were asked to score the intensity of the symptoms on a visual analogue scale from 0 to 5, where 0 was no discomfort at all and 5 was the most severe pain the patient had ever experienced, during disinfection of the skin first and then during disinfection of the conjunctival sac. Then the clarity of the cornea was assessed by the surgeon and an observer specialist throughout surgery. The corneal haziness was graded from 0 to 5, where 0 was no haziness at all and 5 was marked haziness of the cornea.

All the questionnaires were filled in by a single specialist and all the operations were carried out by the same surgeon. The results were compared with those reported by Trinavarat et al. [1].

Results

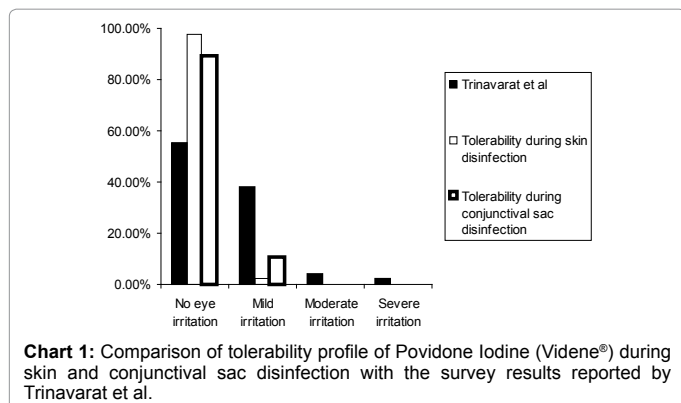
One hundred and thirty two patients participated. Their answers are summarised on Table 1. 116 patients (87.9%) reported no discomfort with application of Povidone Iodine 10% to skin and no discomfort

***Corresponding author:** Theocharis Papanikolaou, 187B Newmarket Road, Cambridge CB5 8HA, United Kingdom, Tel: 447857550840; Email: papanikolaou@doctors.net.uk

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Visual analogue scale discomfort score	Number of patients experiencing discomfort during skin disinfection	Number of patients experiencing discomfort during conjunctival sac disinfection
0	129	118
+1	3	14
+2	0	0
+3	0	0
+4	0	0
+5	0	0

Table 1: Patients' answers on a visual analogue scale regarding discomfort during skin and conjunctival sac disinfection. 0 was no discomfort at all and +5 was the most severe pain the patient had ever experienced.

with application of Povidone Iodine 5% to the eye. Two patients (1.5%) experienced a very mild (+1) skin irritation. Thirteen patients (10%) experienced very mild (+1) and brief conjunctival discomfort. One patient (0.75%) experienced a very mild conjunctival (+1) and a very mild (+1) skin irritation.

With regards to corneal clarity all cases were graded as 0 except five (3.7%) that had mild pre-existing corneal haziness (+1) due to superficial punctate keratitis as a result of poor tear film. The grading in these five cases did not change during the course of the operation.

This is similar to the standard used in which no other toxicity to the ocular surface related to povidone-iodine application was reported. There were no intra-operative, per-operative or post-operative complications.

The tolerability results as compared with the standard used are shown in chart 1. For comparison purposes answers +1 and +2 on a visual analogue scale were both categorised as mild irritation. Answers +3 and +4 were both categorised as moderate irritation and answers +5 on the visual analogue scale were categorised as severe irritation.

Discussion

It has long been standard practice to use 5% povidone iodine solution for pre-operative disinfection of the eye. This practice has been shown to be the most significant factor in reducing the rates of bacterial endophthalmitis after cataract surgery and received the intermediate clinical recommendation of B, in a literature review article by Ciulla et al. [2].

It has been the only significant factor until recently when the use of intracameral cefuroxime at the end of surgery was proven by the ESCRS multi-center study to reduce the risk of occurrence of postoperative endophthalmitis [3].

The benefit of using povidone iodine as preoperative prophylaxis greatly exceeds its potential local side effects which are rare, bearing in mind the potentially detrimental outcome of postoperative

endophthalmitis to the eye and vision. The use of sterile 5% povidone iodine is also supported in patients with iodine, IVP dye or seafood allergies while in known cases of povidone iodine dermatitis, an alternative skin preparation with aqueous chlorhexidine and conjunctival antibiotic prophylaxis should be considered [4].

Povidone iodine has been shown to have very good tolerability and safety profile as reported by Trinavarat et al. in a survey of 2,572 patients [1], which we used as a standard for this audit.

In that survey less patients (55.4%) reported no eye irritation and more patients (38%) reported mild irritation in comparison to our results. Moderate to severe irritation was also reported in 6.6% while we did not have any cases of moderate or severe irritation.

Our results show higher tolerability profile even though our sample was much smaller comparing to the standard.

There has been some controversy with regards to which preparation of povidone iodine should be used.

Until recently there have been two preparations available. Betadine® and Videne®.

Both these preparations contain povidone iodine 10% as their active ingredient.

The main difference is regarding the ammonium salt of alkyl phenol ether sulphate in Videne® that has been quoted as the reason that it should not be substituted for Betadine® for pre-operative disinfection of the eye [5].

Ghosh et al noticed over a two month period that their patients were complaining of stinging pain when Videne® was applied in spite of adequate instillation of topical anaesthesia in the eye and he argues that the other ingredients in the Videne® antiseptic solution are the cause.

However, the 10% concentration of the solution that he used is not the recommended concentration of povidone iodine for disinfection of the eye prior to cataract surgery.

Furthermore the authors do not specify the total number of patients that were prepared with Videne® and they only mentioned that at some stage four consecutive patients complained of intense burning sensation which could have something to do with the application of the anaesthetic eye drops on that particular day.

They also stated that in the instructions for Videne® and in the precautions section it was written "if you get this product in your eye, cleanse with large quantity of running water and seek medical attention".

The argument to that is that in the drug fact sheet for Betadine® and in the warnings section it is stated that Betadine® solution should not be used in the eyes, which clearly refers to the 10% concentration produced by the company, while in ophthalmic practice the product is diluted 50:50 with sterile water, normal saline or balanced salt solution to form a solution containing 5% povidone iodine.

Povidone iodine in itself has been shown to be toxic to the corneal endothelium in animal models [6] which is why it is only used for pre-operative preparation of the eye before cataract surgery and care is taken to thoroughly rinse it off the eye before the anterior chamber is entered.

It has also been shown to have a harmful effect on the intraocular lens implant causing opacification, another reason that it is recommended to avoid using povidone iodine as prophylaxis against infection at the

conclusion of cataract surgery and great care should be taken to ensure complete wound closure at the end of the operation [7].

Conclusion

Our audit results regarding the use of povidone iodine in the form of Videne® in the recommended 5% concentration as a preparation for disinfection of the eye prior to cataract surgery is that it is well tolerated by patients causing no discomfort at all in almost 90% of patients while at the same time it does not compromise the safety of the operation since it does not interfere with the clarity of the cornea. We therefore recommend Videne® for preoperative disinfection in ocular surgery.

References

1. Trinavart A, Atchaneeyasakul LO, Nopmaneejumrulers C, Inson K (2006) Reduction of endophthalmitis rate after cataract surgery with preoperative 5% povidone-iodine. *Dermatology* 212: 35-40.
2. Ciulla TA, Starr MB, Masket S (2002) Bacterial endophthalmitis prophylaxis for cataract surgery: an evidence-based update. *Ophthalmology* 109: 13-24.
3. ESCRS Endophthalmitis Study Group (2007) Prophylaxis of postoperative endophthalmitis following cataract surgery: results of the ESCRS multicenter study and identification of risk factors. *J Cataract Refr Surg* 33: 978-988.
4. Canadian Ophthalmological Society Cataract Surgery Clinical Practice Guideline Expert Committee (2008) Canadian Ophthalmological Society evidence-based clinical practice guidelines for cataract surgery in the adult eye. *Can J Ophthalmol* 43: S7-57.
5. Ghosh YK, Ahluwalia H, Beamer J (2006) Povidone-iodine antisepsis before ophthalmic surgery. *Anaesthesia* 61: 1128-1129.
6. Naor J, Savion N, Blumenthal M, Assia EI (2001) Corneal endothelial cytotoxicity of diluted povidone-iodine. *J Cataract Refr Surg* 27: 941-947.
7. Goel S, Kolli LR, Desai SP, Kumar A, Gauba V, et al. (2008) Povidone iodine causes opacification of silicone intraocular lens implants. *Acta Ophthalmol* 86: 773-777.