



Participant Information Sheet

Study Title

“Defining the impact of topical non-steroidal anti-inflammatory drugs on renal function, a survey of Australasian Renal and Rheumatology Specialists”

Abbreviations

NSAID: Non-steroidal anti-inflammatory Drug

eGFR: estimated Glomerular Filtration Rate (using Creatine Clearance)

CKD: Chronic Kidney Disease

Dear member of the Australian Rheumatology Association,

I thank you kindly for your time and assistance in this study, it is much appreciated.

I am inviting you to partake in a survey that will add valuable information towards assessing the impact of topical non-steroidal anti-inflammatory drugs (NSAIDs) use on renal function and prescribing practices of topical NSAIDs within Australasia.

A link to the survey is provided below:

www.surveymonkey.com/r/BZT5FV7

Aim

The aims of this study are:

- To search for adverse renal outcomes of topical NSAIDs within Australasia.
- To define prescribing practices of topical NSAIDs with Australasia.

Method

A survey has been forwarded to members of the Australian Rheumatology Association (ARA) and the Australian and New Zealand Society of Nephrology (ANZSN).

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The survey consists of 12 questions and should take up to 10 minutes to complete. It is voluntary and anonymous. It may be stopped at any time, or completed at a later date.

Background

Efficacy of topical NSAIDs

Topical NSAIDs have shown to be a valuable treatment option in musculoskeletal conditions. With data to support their use in acute and chronic musculoskeletal pain^{1,2}.

In the setting of chronic pain, when used for hand and knee osteoarthritis³, they have been found to be as efficacious as oral NSAIDs and can be considered as an alternative, when there is concern regarding side effects.

However, the question remains, what is their potential for causing adverse renal outcomes?

Effect of topical NSAIDs on renal function

Two distinct mechanisms underlie NSAIDs ability to cause renal impairment:

The first is an idiosyncratic reaction, causing interstitial nephritis and/or a glomerular nephropathy, a mechanism that does not appear to be dose dependent^{4,5}. This is a rare complication, though has been reported⁵⁻⁷.

The second is due to inhibition of prostaglandin synthesis; required for renal solute homeostasis and maintenance of renal blood flow. This is thought dose dependent⁵.

As topical preparations reach a lower plasma concentration compared to oral NSAIDs, the magnitude of the latter effect should be minimal.

A review of the literature reveals one clearly documented case of acute renal failure due to this mechanism⁸. This occurred when topical Ketoprofen, a drug that is renally cleared, was used in a patient with CKD. The serum level of ketoprofen was found to be similar to that seen in oral dosages, likely due to failure to clear the drug.

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It is possible that the low incidence of adverse renal outcomes is due to topical NSAIDs having a superior safety profile. However, other factors warrant further consideration.

Reporting of adverse outcomes

It has been shown that medical physicians under report adverse side effects⁹. Reasons for this include lack of knowledge, ignorance of need to report, time constraints, diffidence, insecurity, complacency and indifference⁹.

Minimal reports of adverse renal outcomes from topical NSAIDs may be due to under reporting.

Prescribing Practices

Prescribing practices of topical NSAIDs are not well known, especially in patients with CKD.

As topical NSAIDs are available without prescription, they may be being used frequently and the impact on their renal function is minimal or unknown.

Alternatively, it is plausible that topical NSAIDs are infrequently prescribed or used, especially in patients with CKD, which accounts for the low incidence of adverse outcomes.

Hypothesis

Incidence of adverse outcomes may be under reported accounting for the low number of adverse renal events.

The low incidence of adverse renal outcomes may be due to topical NSAIDs being used infrequently, especially in patients with chronic kidney disease.

This study aims to provide further information to address these issues.

Participant Involvement

Participants are asked to please click on the attached directory in the invitation email to begin the survey.

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Benefit of the study

This study will add important information to the knowledge of the impact of topical NSAIDs on renal function as well as current prescribing practices of topical NSAIDs within Australasia.

This will assist treating clinicians in decision making and provide a platform for further research into this field.

Consent

As the survey is voluntary, consent to partake is assumed if the survey is submitted.

Harms of the study

Participation is voluntary. The questionnaire should cause minimal harm to participants. If you at any time feel uncomfortable or do not want to complete the questionnaire, you are not obligated to do so.

It is acknowledged that the survey will take a short period of time to complete, however will contribute greatly to this field of research.

The survey will be anonymous and all results from the survey will be kept confidentially on the primary and associate investigators work computer at Townsville Hospital, as well as the primary investigators private USB, both password protected; for a period of 5 years after the results are analysed.

There will be no link to your personal details as the survey is anonymous.

As the survey is anonymous, once submitted, the results cannot be changed or retracted.

Funding

This study will be funded by the Primary Investigator and the Rheumatology Department of Townsville Hospital in kind. This study has no independent financial support.

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Study findings

Results will be submitted for publication in a peer reviewed journal and will be presented at a state or national meeting.

Questions

If you would like to find out the results of the study you have participated in, please contact the primary author via email (see below) for questions relating to the research.

If there are any concerns or complaints, please contact the Townsville Ethics Committee (see below).

Primary Investigator and study contact-

For research related questions

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Ethics Committee- HREC Contact

For concerns and complaints

Townsville Hospital and Health Service Human Research Ethics Committee

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Email: TSV-Ethics-Committee@health.qld.gov.au

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Study Centre

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