TOPHIP Final Report
23rd November 2018

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EudraCT 2017-000178-13

How Effective are Topical NSAIDs in the Treatment of Hip Osteoarthritis: An *In Vivo* Study in Patients Undergoing Total Hip Arthroplasty (TOPHIP)

Background and Aim

Multiple topical NSAID preparations are available and licenced for the treatment of pain and inflammation in patients with osteoarthritis (OA). Based on an extensive literature review, a recent NICE recommendation advocated the usage of topical nonsteroidal anti-inflammatory drugs (NSAIDs) ahead of oral NSAIDs in the treatment of patients with hand or knee OA (NICE, 2014). It was felt that they had similar analgesic properties to paracetamol, and avoided the potential gastric or renal side-effects associated with oral NSAID use.

There is a paucity of data surrounding the use of topical NSAIDs in patients with hip OA, and hence their use in this situation was not recommended within the NICE guidelines. This may be neglecting a potentially useful analgesic option and is founded on the untested assumption that the hip joint is too deep for topical preparations to penetrate.

The purpose of this mechanistic study was to challenge this assumption and assess whether topical NSAIDs penetrate the hip joint. The primary outcome measure was the concentration of diclofenac in the joint fluid and synovial tissue removed at surgery as part of the procedure.

Methods

Recruitment was from patients seen in the elective orthopaedic and pre-assessment clinics at the Royal Bournemouth Hospital. At a visit three days before routine hip replacement, participants were asked to apply 4g of diclofenac gel to a site marked out by the investigator with a permanent marker (ultimately removeable with alcohol) four times a day for the three days leading up to the surgery. The final application was timed for two hours prior to surgery. Participants were invited not to use any other form of NSAID during the trial, or to apply the gel to areas other than the hip due for surgery.

Patients' diaries were checked for compliance on the day of surgery. The last application of gel was applied two hours prior to surgery. A venous blood sample was taken at the time of surgery to determine plasma levels of the NSAID, and tissue and fluid specimens were taken from joint fluid and synovial tissue removed as part of the procedure.

Results

Two patients consented to participate in the study. One participant was withdrawn prior to the intervention as they did not proceed to surgery. The second participant had the intervention as described, and their samples were analysed at the laboratory.

In October 2018 the lead at the laboratory resigned, and no replacement was found. The Chief Investigator therefore terminated the study early as no further samples could be analysed. The one sample analysed could not be validated, as no further samples were analysed, and no results could be obtained from the study.

Dissemination

There were no findings from the study, so these could not be disseminated.
The participant who had the intervention has been telephoned, and the reasons for closing the study explained.