

health
technology
assessment



EXECUTIVE
SUMMARY

MISOPROSTOL IN
PREGNANCY

HEALTH TECHNOLOGY ASSESSMENT UNIT
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH
MOH/PAK

EXECUTIVE SUMMARY

INTRODUCTION

In Malaysia, the commonly used prostaglandins are Gemeprost (Cervagem[®]) and Dinoprostone (Prostin[®]). Although effective and safe, they are expensive and require special storage (Song J 2000). The search for an effective, easily stored, and affordable cervical ripening and uterotonic agent has led to the use of misoprostol.

Misoprostol has been approved (licensed) to be taken orally for the prevention and treatment of gastric ulcers associated with the use of non steroidal anti inflammatory drugs. This drug is registered by the Drug Control Authority of Malaysia for the same indication. Misoprostol has not been approved for any other indications. Use under these circumstances would be considered off label. Unlike the off label use of other drugs, the use of misoprostol for labor induction has sparked considerable controversy.

POLICY QUESTION

The Obstetrical and Gynecological Society of Malaysia requested a health technology assessment be carried out on the use of “Misoprostol in Pregnancy”. The reason for such a request is recently there has been wide interest by the media on the alleged misuse and the alleged dangers of misoprostol.

TARGET AUDIENCE

This report is meant for policy makers to consider allowing the use of misoprostol on pregnant mothers.

OBJECTIVES

To determine safety, effectiveness, cost effectiveness and legal aspects of misoprostol for various uses in the first, second and third trimester for cervical ripening and induction of labour ~~and~~ as well as the management of post partum hemorrhage.

RESULTS

MISOPROSTOL IN THE FIRST TRIMESTER

Effectiveness

The evidence suggests that in the first trimester, misoprostol is an effective cervical priming agent prior to surgical abortion. It is as effective as gemeprost when used for this purpose. It is also effective in evacuating the uterus in missed abortions. There is limited evidence to support its use in incomplete abortions and as an abortifacient.

Safety

There are studies that found an association between the use of misoprostol for attempted abortion and subsequent Mobius syndrome in live born infants. However there is a need for proper large controlled trials to confirm whether this is a strong association of correlation or not.

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MISOPROSTOL IN THE SECOND TRIMESTER

Effectiveness

For second trimester abortions, there is insufficient evidence for effectiveness of misoprostol as a cervical priming agent. However, there is sufficient evidence for its effectiveness for termination of pregnancy and it is also cost effective.

MISOPROSTOL FOR CERVICAL RIPENING AND INDUCTION OF LABOUR

Effectiveness

In the third trimester, there is sufficient evidence of effectiveness for oral misoprostol for induction of labour. However, the data on optimal regimens are lacking.

Safety

There is evidence that demonstrates that effective oral regimens of misoprostol result in unacceptably high incidence of complications such as uterine hyperstimulation and possibly uterine rupture. There is insufficient large clinical trials to assess maternal and perinatal outcomes.

MISOPROSTOL IN POST PARTUM HAEMORRHAGE

Effectiveness

There is insufficient evidence to support the use of misoprostol in prevention of postpartum hemorrhage.

Safety

A number of studies have reported concerns with the usage of misoprostol in third stage of labour.

COST EFFECTIVENESS

There is sufficient evidence that demonstrates that it is a cost effective alternative to use misoprostol in the first trimester, second trimester and third trimester.

LEGAL IMPLICATIONS

From the legal aspect, misoprostol cannot be used in pregnancy since it has been registered only for treatment of gastric and duodenal ulcers refractory to H₂-receptor antagonists

RECOMMENDATIONS

Based on the current evidence to date, there is sufficient safety and legal concerns not to recommend misoprostol for cervical priming, termination of pregnancy, induction of labour or postpartum hemorrhage