Microarray Patch for Treatment of Neonatal Sepsis

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Our Solution

Microarray patches consist of an array of micro-scaled projections arranged on a flexible baseplate. Upon application of the patch, the tiny projections painlessly pierce the outer layer of the skin. Once inserted, the microarray imbibes interstitial fluid and swells, opening up a continuous aqueous network within the skin (Fig 1). The interstitial fluid causes dissolution of the antibiotic-containing reservoir with diffusion of the drug through the microarray patch and into the rich dermal microcirculation. The projections of the microarray patch are so short that they do not stimulate any pain receptors or touch any blood vessels so are pain-free and do not induce any bleeding. Following removal of the patch, it can be disposed off in a general waste bin. Due to the swelling nature of the projections once removed, they are soft and cannot be reinserted into the skin and therefore do not pose a sharps hazard.

Benefits of Microarray Patches

- Easy to use
- Reduced wastage
- Increased caregiver acceptability
- Sharps injury prevention
- Bypassing GI tract could extend life of antibiotics
- Bypassing GI tract does not kill gut flora thus reducing risk of necrotizing enterocolitis

Examples of Microarray Patches

- Ibuprofen Sodium
- Amoxicillin
- Gentamicin
- Insulin
- Hydrocortisone
- Doxepin Hydrochloride

Microarrays have been combined with drug-containing reservoirs to form integrated patches. Various compounds have been formulated for delivery using microarrays, each with different delivery challenges. Following extensive chemical development and in vitro testing, these patches were applied to an animal model with respective drug detected in plasma, demonstrating their efficacy and potential as a novel drug delivery platform.

Project Progress

Work to date

- Development and validation of analytical methods for detection and quantification of gentamicin and amoxicillin in multiple matrices to ICH standards
- Formulation, fabrication and characterisation of gentamicin-containing lyophilised reservoirs

Ongoing and Future work

- In vitro permeation studies of combined gentamicin and amoxicillin microarray patch
- In vivo delivery studies of amoxicillin and gentamicin from microarray patch
- Microarray patch storage stability studies
- In vivo infection challenge studies to common causative pathogens of neonatal sepsis
- Interviews with local experts in paediatric & health care in low-resource countries
- Microarray patch usability testing

Current treatment options

The World Health Organization currently recommends:

- Hospitalization for 7-10 days and treatment with penicillin and gentamicin delivered intravenously or by intramuscular injection (preferred)

Alternative outpatient care:

- Intramuscular gentamicin and oral amoxicillin

Limitations of recommended treatment:

- Hospitalization is expensive with many deaths occurring in the community due to cost of treatment
- Trained health care workers required
- Intramuscular injection is painful and destressing for both child and parents
- Risk of transmission of blood borne infections
- Access to clean drinking water required for reconstitution of amoxicillin
- Amoxicillin suspension stored in refrigerator

References


Problem

Neonatal Sepsis

Approximately 421,000 new-borns die each year from sepsis

Neonatal Infections

Account for 26-36% of global neonatal deaths in low-middle income countries

2012 survey: only 2 of 59 ‘priority countries’ have official policies for treating infections such as neonatal sepsis

Childhood mortality

6% of deaths in children under 5 are due to sepsis, despite presence of effective treatments.