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Screening per GBS: utilità e controversie

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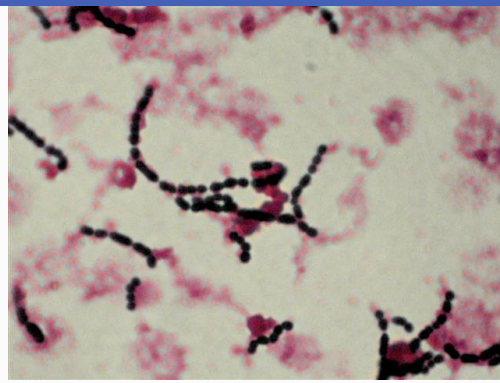
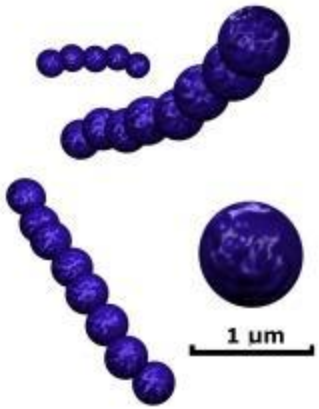
Streptococcus agalactiae di gruppo B

- Batterio Gram + piogenico, anaerobio facoltativo
- Tratto gastro-enterico e urogenitali femminile
- Veicolo asintomatico
- Colonizzazione: cronica, transitoria o intermittente
- 10-37% delle donne gravide sono portatrici
- 60-75%: rimane positiva fino alla fine della gravidanza





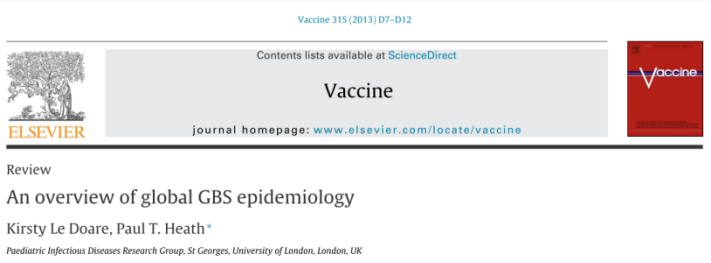
Streptococcus agalactiae

Conseguenze della colonizzazione materna

- Asintomatica
- Corionamniosite
- Parto pretermine
- Endometrite
- Infezioni del tratto urinario

Infezione neonatale da SGB

- 50% dei neonati da madri infette contraggono l'infezione durante il passaggio attraverso il canale del parto
- Soltanto l'1-2% di questi sviluppa una malattia sistemica grave
- Prevalenza: 0.5-2% dei nati vivi
- I neonati da parto pretermine o con basso peso alla nascita hanno maggio rischi di sviluppare infezioni da SGB (probabile carente risposta immunitaria e fattori ambientali sfavorevoli) → outcome peggiore


Vaccine 31S (2013) D7–D12

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Vaccine

journal homepage: www.elsevier.com/locate/vaccine

ELSEVIER

Review

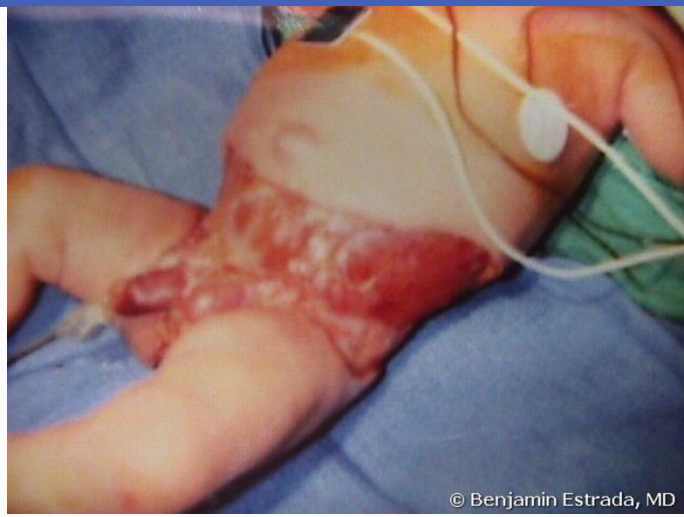
An overview of global GBS epidemiology

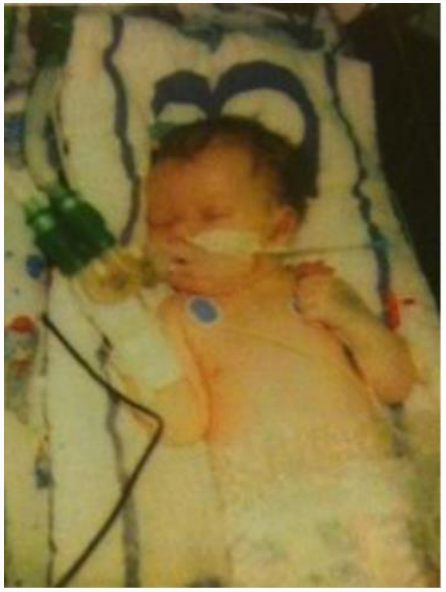
Kirsty Le Doare, Paul T. Heath*

Paediatric Infectious Diseases Research Group, St Georges, University of London, London, UK

Infezione neonatale da SGB

- Principale causa di **sepsi** e **meningite** neonatali nei primi tre mesi di vita
- Coloro che sopravvivono possono sviluppare **disabilità permanenti** quali perdita di vista e udito, ritardo dello sviluppo neurologico, paralisi cerebrale





Infezione neonatale da SGB

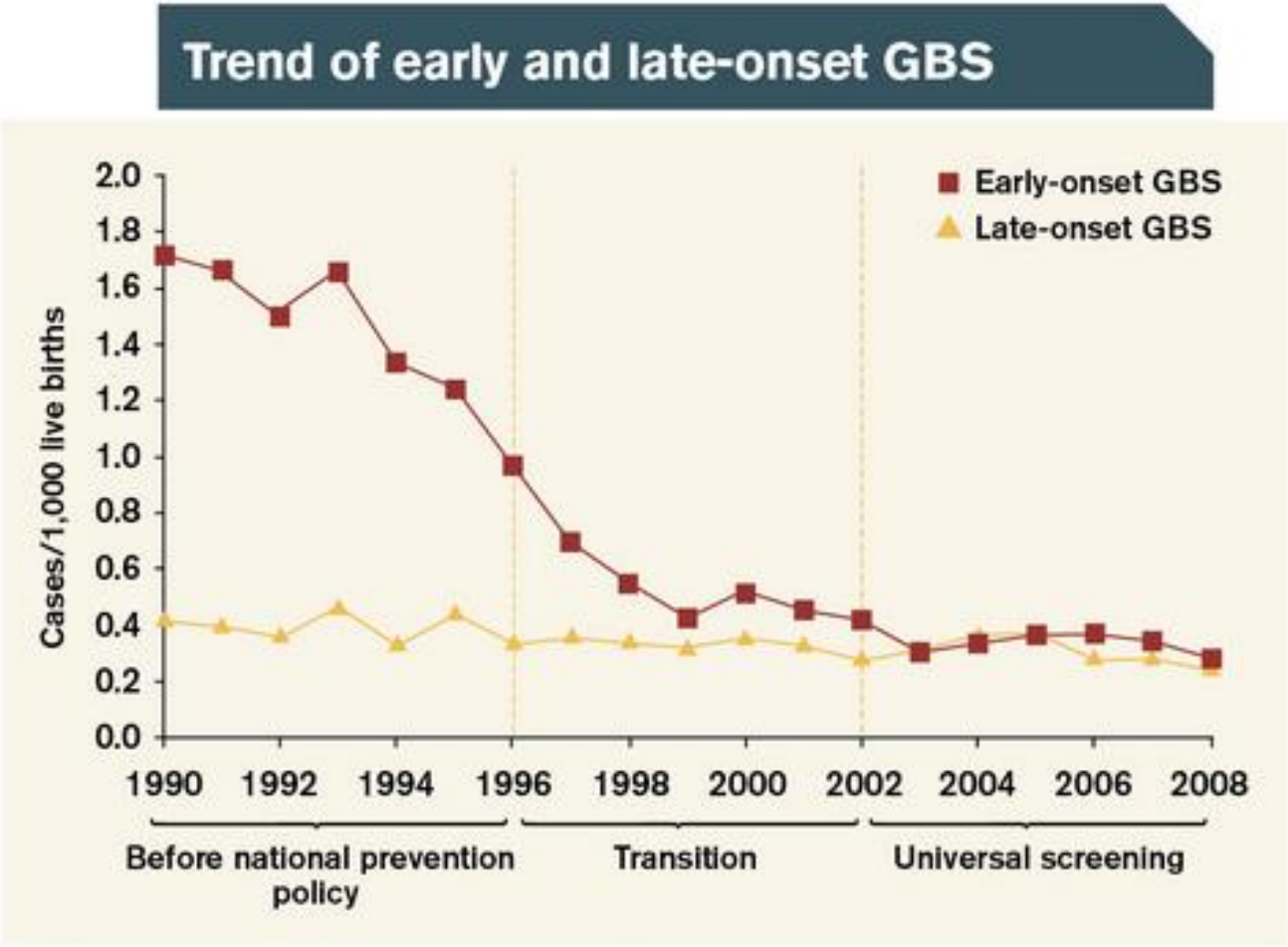
Early onset

- **Entro 72h** positività all'emocoltura o alla coltura del liquido cefalo-rachidiano.
- Modalità di trasmissione quasi esclusivamente **verticale** (canale del parto)
- Nel 90% dei casi la malattia diventa evidente entro 12 ore dalla nascita
- **Clinica**: sepsi, polmonite, meningite
- Tasso di mortalità neonatale: **4-10%**

Infezione neonatale da SGB

Late onset

- **Oltre 72h** dal parto positività all'emocoltura o alla coltura del liquido cefalo-rachidiano
- Modalità di trasmissione **verticale** o **orizzontale** (fonti nosocomiali o comunità)→spesso la fonte di contagio non è chiaramente nota.
- Clinica: sepsi e meningite. Polmonite, infezioni del tessuto osseo, articolare o dei tessuti molli sono rare evenienze.
- Tasso di mortalità neonatale: **2-6%**



Incidence of early-and late-onset GBS disease in the Active Bacterial Core (ABC) surveillance areas from 1989 to 2008. The yellow line represents late-onset disease; the red line represents early-onset disease.

Attuali strategie di screening

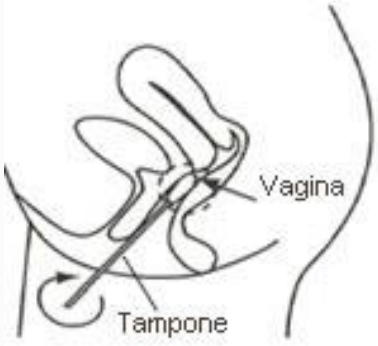
Center for Disease Control (CDC) 2002

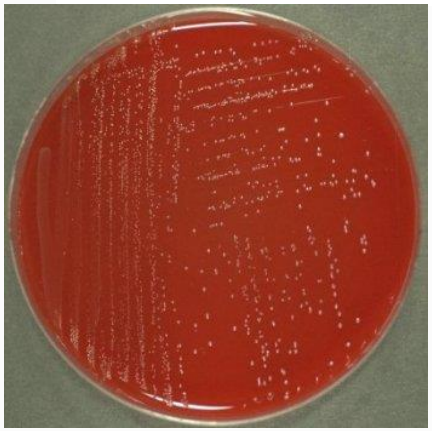
- **Screening colturale universale** di tutte le donne all'ultimo mese di gravidanza e uso di una **profilassi antibiotica intrapartum** (intrapartum antibiotic prophylaxis, IAP)

- Approccio non omogeneo in tutta l'Europa→ screening modificati, somministrazione della IAP esclusivamente alle donne con specifici di rischio

Screening colturale universale antepartum

- Esame colturale di un tampone vaginale e rettale (combinato) eseguito tra 35 e 37 settimane
- Profilassi antibiotica intrapartum (IAP) somministrata alle donne positive o a quelle che non lo hanno eseguito
- Tale metodo implica spesso un'esposizione elevata e spesso non necessaria ad antibiotici →resistenze e rischio aumentato di reazioni anafilattiche





Screening colturale universale antepartum

La **colonizzazione intermittente** può dare dei risultati falsi positivi o falsi negativi

- Possibile esposizione non necessaria ad antibiotici
- Mancata diagnosi di circa il 60% di neonati affetti da EOI nati da madri negative allo screening

Screening basato sui fattori di rischio per EOI

- Precedente neonato affetto da EOI
- Batteriuria da SBG in gravidanza in corso
- Parto pretermine < 37 sett
- PROM > 18 h e/o febbre in travaglio > 38° C

Vantaggio→ limitazione dei costi, bassa esposizione agli antibiotici

Svantaggio→ 40-60% dei neonati con EOI le cui madri non presentano alcun fattore di rischio

Kolkman et al. BMC Pregnancy and Childbirth 2013, 13:155
http://www.biomedcentral.com/1471-2393/13/155

BMC Pregnancy & Childbirth

STUDY PROTOCOL Open Access

Implementation of a cost-effective strategy to prevent neonatal early-onset group B haemolytic streptococcus disease in the Netherlands

Diny GE Kolkman[1,2*], Marlies EB Rijnders[1], Maurice GAJ Wouters[2], M Elske van den Akker-van Marle[3], CPB Kitty van der Ploeg[1], Christianne JM de Groot[2] and Margot AH Fleuren[4]

Abstract

Background: Early-onset Group B haemolytic streptococcus infection (EOGBS) is an important cause of neonatal morbidity and mortality in the first week of life. Primary prevention of EOGBS is possible with intra-partum antibiotic prophylaxis (IAP.) Different prevention strategies are used internationally based on identifying pregnant women at risk, either by screening for GBS colonisation and/or by identifying risk factors for EOGBS in pregnancy or labour. A theoretical cost-effectiveness study has shown that a strategy with IAP based on five risk factors (risk-based strategy) or based on a positive screening test in combination with one or more risk factors (combination strategy) was the most cost-effective approach in the Netherlands. IAP for all pregnant women with a positive culture in pregnancy (screening strategy) and treatment in line with the current Dutch guideline (IAP after establishing a positive culture in case of pre-labour rupture of membranes or preterm birth and immediate IAP in case of intra-partum fever, previous sibling with EOGBS or GBS bacteriuria), were not cost-effective. Cost-effectiveness was based on the assumption of 100% adherence to each strategy. However, adherence in daily practice will be lower and therefore have an effect on cost-effectiveness.

Method/Design: The aims are to: a.) implement the current Dutch guideline, the risk-based strategy and the combination strategy in three pilot regions and b.) study the effects of these strategies in daily practice. Regions where all the care providers in maternity care implement the allocated strategy will be randomised. Before the introduction of the strategy, there will be a pre-test (use of the current guideline) involving 105 pregnant women per region. This will be followed by a post-test (use of the allocated strategy) involving 315 women per region. The outcome measures are: 1.) adherence to the specific prevention strategy and the determinants of adherence among care providers and pregnant women, 2.) outcomes in pregnant women and their babies and 3.) the costs of each strategy in relation to the effects.

Discussion: This study will provide recommendations for the implementation of the most cost-effective prevention strategy for EOGBS in the Netherlands on the basis of feasibility in daily practice.

Trial registration: Dutch Trial Register, NTR3965

Keywords: Early-onset Group B streptococcus, Prevention, Dutch maternity care, Implementation, Guidelines

Modalità di somministrazione della IAP

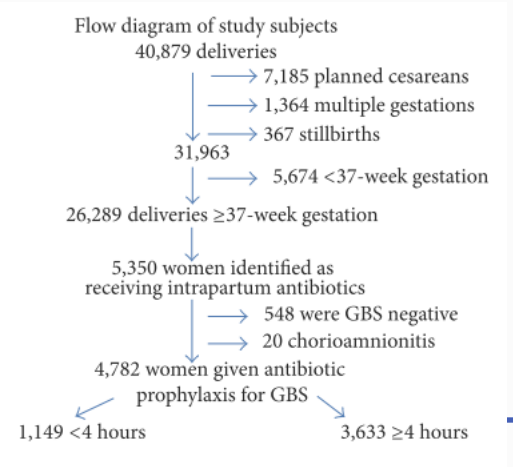
- Raccomandata **4 ore** prima del parto
- Intervallo tra inizio travaglio e parto di sole 2 ore fornisce comunque una copertura accettabile (?)
- Se intervallo < 2 ore → necessario informare il pediatra
- Non necessaria in caso di taglio cesareo elettivo (fuori travaglio e senza rottura prematura delle membrane)

Clinical Study

Duration of Intrapartum Antibiotics for Group B Streptococcus on the Diagnosis of Clinical Neonatal Sepsis

Mark A. Turrentine,[1] Anthony J. Greisinger,[2] Kimberly S. Brown,[2] Oscar A. Wehmanen,[2] and Melanie E. Mouzoon[3]

Background. Infants born to mothers who are colonized with group B streptococcus (GBS) but received <4 hours of intrapartum antibiotic prophylaxis (IAP) are at-risk for presenting later with sepsis. We assessed if <4 hours of maternal IAP for GBS are associated with an increased incidence of clinical neonatal sepsis. *Materials and Methods*. A retrospective cohort study of women-infant dyads undergoing IAP for GBS at ≥37-week gestation who presented in labor from January 1, 2003 through December 31, 2007 was performed. Infants diagnosed with clinical sepsis by the duration of maternal IAP received (< or ≥4-hours duration) were determined. *Results*. More infants whose mothers received <4 hours of IAP were diagnosed with clinical sepsis, 13 of 1,149 (1.1%) versus 15 of 3,633 (0.4%), $P = .03$. Multivariate logistic regression analysis showed that treatment with ≥4 hours of IAP reduced the risk of infants being diagnosed with clinical sepsis by 65%, adjusted relative risk 0.35, CI 0.16–0.79, and $P = .01$. *Conclusion*. The rate of neonatal clinical sepsis is increased in newborns of GBS colonized mothers who receive <4 hours compared to ≥4 hours of IAP.



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Infectious Diseases in Obstetrics and Gynecology
Volume 2013, Article ID 525878, 6 pages
http://dx.doi.org/10.1155/2013/525878

Dosaggi suggeriti

Penicillina G	Dose iniziale 5 milioni di U (3g) im, seguita da 2.5 milioni di U (1.5 g) im ogni 4 ore fino al parto	*Prima scelta*
Ampicillina	Dose iniziale 2 g ev, seguita da 1 g ev ogni 4 ore fino al parto	*Alternativa accettabile*
Cefalotina	Dose iniziale 2g ev, seguita da 1 g ev ogni 8 ore fino al parto	*Basso rischio di reazioni anafilattiche*
Clindamicina	900 mg ev ogni 8 ore fino al parto	*In caso di allergia alla penicillina; 25% di resistenza*
Eritromicina	500 mg ev ogni 6 ore fino al parto	*Non indicato (alto R di resistenze)*
Vancomicina	1 g ev ogni 12 ore fino al parto	*Ultima scelta (effetti collaterali)*

Problematiche connesse alla IAP

- Resistenza alle penicilline
- Anafilassi
- Incremento delle infezioni non da SGB nei neonati a termine
- Incremento delle infezioni da E.Coli e da stafilococchi coagulasi negativi nei nati pretermine e con basso peso alla nascita
- Ritardo nel timing della manifestazione dei sintomi o cambiamenti delle caratteristiche cliniche dell'infezione
- Cambiamenti del *microbioma* del neonato che possono interferire col suo priming immunologico e con lo sviluppo di allergie, asma e obesità nell'infanzia

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Cite this as: Swiss Med Wkly. 2013;143:w13778

Antibiotic resistance patterns among group B Streptococcus isolates: implications for antibiotic prophylaxis for early-onset neonatal sepsis

Federica Capanna[a], *Stephane P. Emonet*[b,c], *Abdessalam Cherkaoui*[b], *Olivier Irion*[a], *Jacques Schrenzel*[b,c], *Begona Martinez de Tejada*[a]

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STUDY/PRINCIPLES: Antibiotic prophylaxis of Group B Streptococcus (GBS) positive women during labour reduces the risk of early-onset neonatal sepsis. Penicillin is the first choice, and clindamycin and erythromycin are second choices for penicillin-allergic women. Resistance to these antibiotics is rising. The aims of this study were to evaluate the rates of clindamycin and erythromycin resistance among GBS-positive isolates cultures from pregnant women in the University Hospital of Geneva and to evaluate the legitimacy of new Centres for Disease Control and Prevention (CDC) recommendations for our context.

METHODS: We collected a vagino-rectal swab from pregnant women at 35–37 weeks gestation. We recovered 124 GBS positive isolates. Identification was based on the characteristic of the colony on the chromogenic agar, the streptococcal agglutination test and confirmation by mass spectrometry. Antimicrobial susceptibility was determined by disk diffusion, according to CLSI guidelines 2010.

RESULTS: The rate of resistance to clindamycin was 28% and to erythromycin was 30%. Only 3 of the 38 erythromycin resistant strains (7.9%) were susceptible to clindamycin, and only 3 out of the 35 clindamycin resistant GBS (8.6%) were identified as "inducible resistance". The rate of co-resistance to clindamycin of erythromycin-resistant strains was 92%. Penicillin remained efficacious in all cases.

CONCLUSION: Rates of clindamycin and erythromycin resistance are also increasing in our context. These antibiotics should not be used for GBS neonatal sepsis prevention, without adequate antimicrobial susceptibility testing. In case of penicillin allergy and lack of antibiogramm, cephalosporins or vancomycin should be used as recommended in CDC guidelines.

Journal of Clinical Microbiology

High Rates of Inducible Clindamycin Resistance among Prenatal Group B Streptococcal Isolates in One Northwest Louisiana Academic Medical Center

Gerald A. Capraro, Ellen D. Rambin, John A. Vanchiere, Joseph A. Bocchini Jr and Janice M. Matthews-Greer
J. Clin. Microbiol. 2013, 51(7):2469. DOI: 10.1128/JCM.00279-13.
Published Ahead of Print 17 April 2013.

- Utilizzo del D-test: test di diffusione mediante doppio disco (ERY-CLI)
- n: 2042
- ERY-resistance: 38%
- CLI-resistance: 21%
- Cefazolina consigliata per pazienti a basso rischio di anafilassi
- Vancomicina consigliata per pazienti ad alto rischioi di anafilassi e presenza di ceppi CLI-resistenti

Nuovi metodi di screening (PCR intrapartum)

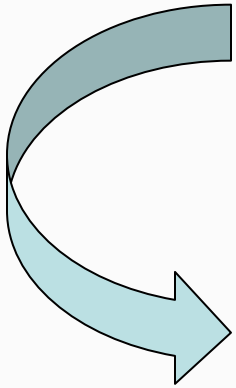
- Test molecolari rapidi basati sulla PCR
- Sensibilità 62.5 - 100 %
- Specificità 84.6 – 100%
- **Eseguibile in breve tempo** prima del parto → può anche essere utilizzata nelle donne non sottoposte precedentemente a screening.
- **Limita l'esposizione non necessaria agli antibiotici**

⇩

- Individua le donne che realmente necessitano della IAP ma risultate negative allo screening universale

Diffusione della PCR intrapartum

- Difficoltà: costi legati all'acquisto di nuove attrezzature
- Diminuzione dei costi limitando la necessità di competenze tecniche ed eliminando la necessità di tecnici di laboratorio



DOI: 10.1111/1471-0528.12138
www.bjog.org

Reduction of the use of antimicrobial drugs following the rapid detection of *Streptococcus agalactiae* in the vagina at delivery by real-time PCR assay

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*These authors contributed equally to the work.

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Reduction of the use of antimicrobial drugs following the rapid detection of *Streptococcus agalactiae* in the vagina at delivery by real-time PCR assay

Objective To assess whether the determination of the presence of group B streptococci (GBS) in the vagina using a rapid polymerase chain reaction (PCR) assay at delivery was able to spare useless antimicrobial treatments, as compared with conventional culture at 34–38 weeks of gestation.

Design Practical evaluation and prospective cost-effectiveness analysis.

Setting A university hospital in France.

Population A cohort of 225 women in labour at the University-Hospital of Saint-Etienne.

Methods Each woman had a conventional culture performed at 34–38 weeks of gestation. At the beginning of labour, two vaginal swabs were sampled for rapid PCR testing and culture. The decision to prescribe a prophylactic antimicrobial treatment or not was taken according to the result of the PCR test. A comparative cost-effectiveness analysis of the two diagnostic strategies was carried out.

Main outcome measures Number of women receiving inadequate prophylactic antimicrobial drugs following each testing strategy, costs of PCR testing and culture, frequency of vaginal GBS, and diagnostic performance of the PCR test at delivery.

Results The percentage of unnecessarily treated women was significantly reduced using the rapid test versus conventional culture (4.5 and 13.6%, respectively; $P < 0.001$). The rate of vaginal GBS at delivery was 12.5%. The incremental cost-effectiveness ratio (ICER) for each inadequate management avoided was €36 and €173 from the point of view of the healthcare system and hospital, respectively.

Conclusions The PCR assay reduced the number of inadequate antimicrobial treatments aimed to prevent the early onset of GBS disease. However, this strategy generates extra costs that must be put into balance with its clinical benefits.

Keywords Cost-effectiveness analysis, group B streptococcus, intrapartum antimicrobial prophylaxis, real-time PCR assay.

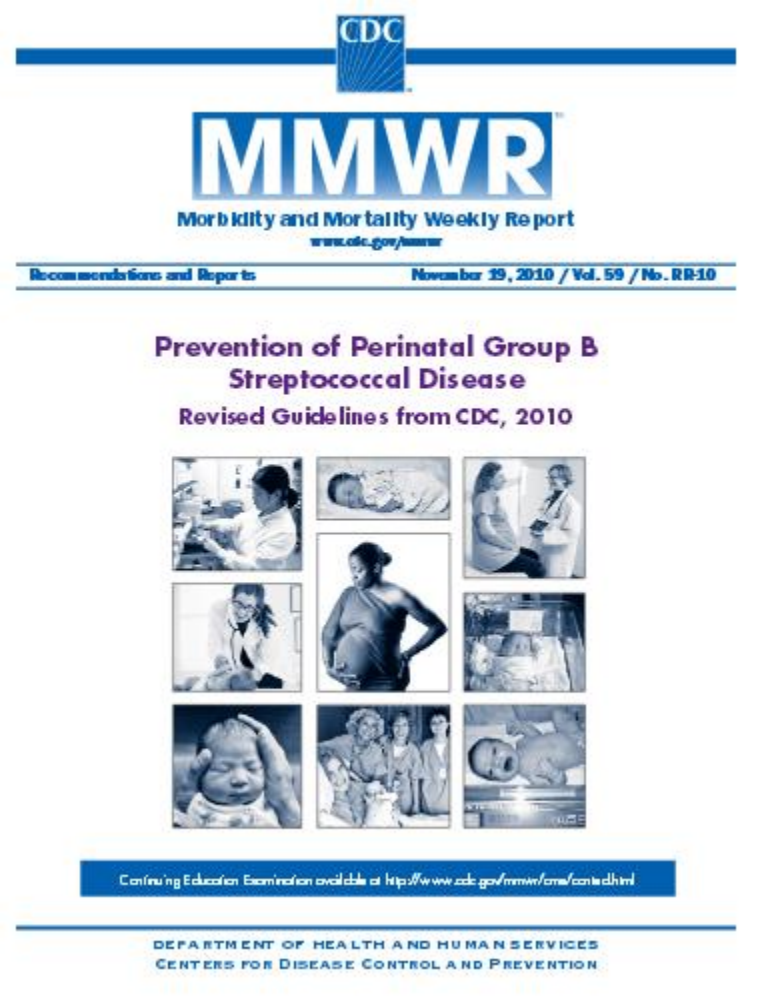
Firenze, 6 – 8 giugno 2013

European Consensus Conference per lo sviluppo di nuovi metodi per lo screening delle infezioni da SGB

Alla luce delle evidenze attuali bisognerebbe prediligere lo screening intrapartum con PCR:

- Identificare la reale colonizzazione al momento del parto
- Evitare l'esposizione non necessaria agli antibiotici da parte delle con test negativo
- Somministrare la IAP in tutte le donne con FdR senza bisogno di eseguire il test
- In caso di parto pretermine o PROM il test dovrebbe essere eseguito in modo da somministrare la IAP solo alle donne realmente positive

Test rapido ideale: quali caratteristiche?



To be clinically useful in the intrapartum period, a screening test for GBS should consist of a **simple bedside kit** that enables labor and delivery staff to perform a test, have a turn-around time of **<30 minutes**, and have a **sensitivity and specificity of ≥90%.** Ideally, a rapid test for intrapartum use also would be able to **detect mutations** likely to confer resistance to clindamycin and/or erythromycin in order to guide antibiotic choice for penicillin-allergic women.

Strategie opzionali per la prevenzione della EOI da SBG ed eventuali trattamenti aggiuntivi alla IAP

Disinfezione locale e a livello vaginale con clorexidina durante il travaglio sia a termine che pretermine

Uguale efficacia nel trattamento a breve termine delle vaginosi e/o nella colonizzazione da SGB o da E.Coli rispetto al trattamento con ampicillina, clindamicina o metronidazolo

Lavande vaginali intrapartum da 120 ml a base di clorexidina diacetato allo 0.2%:

- Riduzione della colonizzazione batterica
- Riduzione della mortalità neonatale
- Riduzione dell'incidenza di sepsi materne e neonatali

Vaccine 31S (2013) D58–D65

Contents lists available at SciVerse ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Review

GBS public awareness, advocacy, and prevention—What's working, what's not and why we need a maternal GBS vaccine

Gina Burns[a,*], Jane Plumb[b]

A B S T R A C T

Group B Streptococcus (GBS) is the most common cause of severe early-onset (0–6 days) infection and a significant cause of serious late-onset (7–90 days) infection in infants. While most babies recover from their GBS infection, some are stillborn, more die in the first weeks of life and others suffer lifelong disability. Despite efforts in many developed countries to prevent these infections, the burden of GBS disease remains significant, particularly among the late onset infections, which are not preventable using current risk-based or screening strategies. Vaccination, once available, could prevent more cases of GBS infection than any other strategy, including preventing preterm labor and stillbirths caused by GBS infection, post-delivery GBS infection in the mother and late-onset GBS infection in the baby. Vaccination would also avoid allergic reactions to antibiotics and concern about the emergence of antibiotic resistant bacteria.

We consider the history of the two largest group B Strep parent organizations (Group B Strep Association USA and Group B Strep Support UK) and the history of GBS prevention in their respective countries. We look at what is needed before a vaccine can be introduced and consider how acceptable a GBS vaccine would be from families' perspective. We also summarize what a perfect GBS vaccine would look like and what we should all strive to achieve.

6. What is missing before a vaccine can be introduced?

Even before a safe and reliable vaccine is available, steps can be taken to facilitate its introduction:

- Standardized definition of disease worldwide.
- Standardized monitoring of disease worldwide.
- Routine prenatal care widely available in which a vaccine can be delivered.
- Education of health professionals and parents and expectant parents about group B Strep and the vaccine.

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Review

GBS public awareness, advocacy, and prevention—What's working, what's not and why we need a maternal GBS vaccine

9. What are the hurdles?

- We do not have a vaccine.
- Education of provider and education of public.
- Acceptance and approval of a GBS vaccine by government health authorities.
- Identification of a leader, such as the World Health Organization, for implementation globally, as well as the identification of an organization to coordinate collection of data, implementation and its effects.
- Unified epidemiology that allows for data comparison and disease

12. Conclusion: what would a perfect GBS vaccine look like?

- The ideal vaccine would prevent pre-term and pre-delivery complications associated with GBS.
- The ideal vaccine would prevent early onset GBS morbidity and mortality in both mother and baby.
- The ideal vaccine would prevent late onset GBS morbidity and mortality in the newborn.
- The ideal vaccine would be administered in early adolescence and would last during childbearing years.
- The ideal vaccine would be safe and have a high level of efficacy.

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Review

Considerations for a phase-III trial to evaluate a group B *Streptococcus* polysaccharide-protein conjugate vaccine in pregnant women for the prevention of early- and late-onset invasive disease in young-infants

Shabir A. Madhi[a,b,c,*], Ziyaad Dangor[b,c], Paul T. Heath[d], Stephanie Schrag[e], Alaine Izu[b,c], Ajoke Sobanjo-ter Meulen[f], Peter M. Dull[f]

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ABSTRACT

In 2010, an estimated 393,000 infection-related neonatal deaths occurred worldwide with Group B streptococcus (GBS) being a leading cause. Prevention of early-onset disease (0–6 days; EOD) is currently focused on intra-partum antibiotic prophylaxis to mothers identified as being at risk; such strategies reduce EOD by 75–80% but are resource-intensive and logistically-difficult to implement in developing countries. Vaccination of pregnant women is an alternate strategy for preventing both EOD and late-onset disease (7–89 days; LOD). A trivalent GBS polysaccharide-protein conjugate vaccine (GBS-CV) composed of capsular epitopes from serotypes Ia, Ib and III is undergoing phase-II evaluation among pregnant women in Europe, North America and Africa. These serotypes cause 70–80% of all invasive GBS disease in early-infancy. Maternal anti-GBS antibodies are associated with protection from EOD, however, since a correlate of efficacy has not been defined, a phase III efficacy trial may be required for licensure. Criteria for selecting appropriate sites include sufficiently high GBS incidence in large birth cohorts, as well as adequate clinical and microbiological diagnostic skills and capacities. Alternate pathways to licensure should be explored, e.g. identification of serological correlates of protection with subsequent phase IV studies establishing vaccine-effectiveness against invasive GBS disease. Conducting a randomized, placebo-controlled efficacy trial, however, has the additional advantage of also being able to evaluate the role of GBS contributing to neonatal culture-negative sepsis, stillbirths, prematurity and low-birth weight.

Conclusioni

- L’attuale debolezza nelle strategie utilizzate per determinare la colonizzazione da SGB in gravidanza ha portato alla ricerca di metodi di screening più accurati

- L’utilizzo di PCR intrapartum ha dimostrato alta sensibilità e specificità nel definire la colonizzazione da SGB in travaglio e sembra essere il migliore metodo di screening
- I paesi europei necessitano di confermare l’economicitò e la fattibilità di tale metodica
- Lo screening universale mediante coltura potrebbe trasformarsi in un test intrapartum affidabile e facile da utilizzare che può diminuire il numero di madri e di neonati trattati con antibiotici sistemici non necessari durante la gravidanza ed il parto