EVMS EM JC CRITICAL REVIEW FORM

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Citation: Kaplan RL, Omphalitis and Concurrent Serious Bacterial Infection. Pediatrics. 2022 May 1;149(5)

Background: Omphalitis is a soft tissue infection involving the umbilicus and the surrounding tissues.

Omphalitis is an uncommon but potentially serious infection that comes with risks of both concomitant serious bacterial infections (SBI) and risks of adverse outcomes. There is currently little evidence available to guide the optimal approach to diagnosis as well as management.

Study Objectives:

To address the gaps above, the study's objectives are to describe the clinical presentation, prevalence of concurrent SBI, and outcomes among infants with omphalitis

Study Methodology:

General: Mulit-center study (28 sites) using the framework of Pediatric Emergency Medicine Collaborative Research Committee (PEMCRC) did a retrospective chart review of infants less than 90 days of age diagnosed with omphalitis over a ten year period (01/2008-12/2017).

Inclusion criteria: Initially, the patients were identified as potentially eligible by searching the electronic health record for the diagnosis code of omphalitis. To further ensure accuracy of the diagnosis, potential subjects were identified by reviewing charts for words closely related to a clinical diagnosis of omphalitis including "umbilicus" + "erythema, induration, flatulence, purulent drainage."

In order to characterize a patient as afebrile or well-appearing, further chart review was necessary. Firstly, subjective descriptors were used to define the general clinical appearance to determine if a patient was well-appearing vs in a state of shock or sepsis, additionally to determine if there was presence of necrotizing soft tissue infection. The general appearance was categorized as well, unwell, or unclear/not documented. If documentation of words such as "well," "well-appearing," "no apparent distress," "playful," were used, the patient was well-appearing. A clinical diagnosis of sepsis or shock was abstracted if "shock," "hypotensive," or the combination of the word "sepsis," and requirement of =/>40cc/kg isotonic fluid boluses was found in the patient's chart. Additionally, if there was evidence of requiring pressors, or low BP (<60 systolic) was documented.

Outcome measures: Primary outcomes were the presence of SBI and adverse events.

SBI defined as bacteremia, bacterial meningitis, or UTI. SBI categorized as present or not.

Adverse events defined as clinical diagnosis of shock, severe or necrotizing soft tissue infection, endotracheal intubation, administration of vasopressors, or death. Adverse outcomes categorized as present, not present, unclear/not documented.

Statistical analysis: Age and lab values presented with medians and interquartile ranges (IQR), and categorical variables (demographics, historical and clinical findings, utilization and cultures, prevalence or SBI, and adverse events) with proportions and 95% binomial confidence intervals (CI).

Randomization and Blinding:

Retrospective study, no randomization or blinding was used.

What were the results:

Among the 566 patients enrolled, median age was 16 days (IQR 8-22 days), 90% were FT gestations without significant past medical history, only 11% had fever at home or in ED, and vast majority (95%) were described as well-appearing on physical exam at presentation when diagnosed with omphalitis.

Blood cultures were obtained in 83% of patients, urine cultures in 58%, and CSF cultures in 39%. Pathogens grew in approximately 1% of blood cultures, 1% of urine cultures (representing 0.5% of all patients), and 1% of CSF cultures were positive (representing 0.4% of all patients). Most patients were hospitalized. 2% had sepsis or shock and 1% had sepsis or shock requiring ICU level of care. Only 2 infants had severe cellulitis or necrotizing soft tissue infection, and there was one death.

Ultrasound was performed on 28% with urachal anomalies found on 26% (representing 7% of the cohort). 3.7% experienced any adverse event described as a positive blood, urine, or CSF culture or clinical diagnosis of sepsis or shock, necrotizing soft tissue infection, endotracheal intubation, vasopressor use or death.

In this large multicenter study on a large cohort of infants with omphalitis, SBI and adverse events were uncommon with bacteremia in approximately 1% and sepsis or shock requiring ICU level of care in another approximately 1%. SBIs occurred only in infants younger than 28 days.

While all febrile infants aged 21 days and younger require cultures of blood, urine, and CSF, the study suggests that routinely obtaining CSF cultures may not be indicated in well-appearing afebrile infants with omphalitis 21 days old and younger. Additionally, routine blood and CSF cultures may not be necessary in afebrile well-appearing infants older than 21 days. Ultrasound and urine cultures should be obtained in all ages given the association with urachal abnormalities.

Applicability to my patient care

Uncommon diagnosis but one that certainly prompts discussion amongst providers of how to proceed in regard to how much of a workup is to be done. This helps clarify some of those questions by presenting risks of SBI with a fairly sizable n.

Strengths

Useful for a rare diagnosis to use a retrospective study. Since the patient was seen and general appearance documented, there is lower likelihood of bias from the provider vs thinking back about a patient who fell into the adverse outcome group and was then recalled as unwell appearing.

Weaknesses

Given low frequency of adverse outcomes and retrospective nature of study, it was unable to evaluate and identify risk factors for the presence of SBI. Additionally, the study did not correlate patient outcomes with inflammatory markers (diagnostic ability to apply inflammatory markers with the disease state) which are commonly used in pediatrics

My Clinical Bottom Line

Prevalence of concurrent SBI and adverse outcomes is very low, depending on age, routine cultures may not be needed in all well-appearing, afebrile patients with omphalitis. Likely would obtain ultrasound and urine cultures with all patients no matter what age given high association with urachal anomalies but with well appearing and afebrile patients <21 days could hold off on CSF cultures and >21 days hold off on blood and CSF cultures (again, if afebrile and well-appearing).