



Review article

Contraceptive safety among women with cystic fibrosis: a systematic review[☆]

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Abstract

Background: With dramatic improvements in life expectancy for cystic fibrosis (CF) patients, contraception for women with CF has become an important issue. There are theoretical concerns that hormonal contraceptive use among women with CF may impact disease severity or risk for other adverse health outcomes, including thrombosis and poor bone health, as well as concerns that malabsorption or altered drug metabolism might impact contraceptive effectiveness.

Objective: To evaluate evidence on the safety and effectiveness of contraceptive methods among women with CF.

Search Strategy: We searched the PubMed database for all articles published from database inception through October 2015.

Selection Criteria: We included studies that examined measures of disease severity, other health outcomes or indicators of contraceptive effectiveness among women with CF initiating or continuing a contraceptive method.

Results: Seven studies met our inclusion criteria. Three observational studies of fair to poor quality suggest that use of oral contraceptives (OCs) does not negatively impact CF disease severity, defined as changes in pulmonary function, number of exacerbations or need for intravenous antibiotics. Three small studies of poor quality reported on contraceptive failure among women with CF using combined hormonal contraceptives (combined OCs, patch or ring). One pregnancy was reported in a patch user out of 43 hormonal contraceptive users across all studies. One pharmacokinetic study reported that women with CF achieve steroid hormone plasma concentrations similar to healthy women after ingestion of combined OCs.

Conclusions: Limited evidence suggests that hormonal contraceptive use does not negatively impact disease severity among women with CF and that hormonal contraceptive effectiveness is not impaired by CF. Studies were limited by small sample sizes and short duration of follow-up. No studies examined the effect of hormonal contraception on thrombosis or bone health among women with CF.

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Keywords: Contraception; Cystic fibrosis; Safety; Effectiveness; Systematic review

1. Introduction

Cystic fibrosis (CF) is an autosomal recessive disease affecting epithelial tissues throughout the body caused by mutations in the gene which encodes for the CF transmembrane conductance regulator (CFTR) protein, which regu-

lates chloride ion transport across cell membranes. It is a multisystem disorder characterized primarily by thick sticky mucus in the lungs, pancreas and other organs. In the United States, estimates from registry data indicate that approximately 30,000 US children and adults have CF, with approximately 1000 new cases diagnosed each year [1]. While CF is a very serious and life-threatening condition, advances in diagnosis and treatment have resulted in a dramatic improvement in life expectancy. In recent years, the median predicted survival improved by almost 10 years, from 31.3 years in 2002 to 40.7 years in 2013 [1]. With this improving prognosis, more women with CF are reaching

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reproductive age and, as a result, issues related to reproductive health, including contraceptive use, are becoming increasingly important.

There are several theoretical concerns regarding contraceptive use among women with CF. Some studies suggest that endogenous sex hormones may impact lung function or the clinical status of CF patients by influencing transepithelial ion transport, infection or inflammation [2]. Additionally, CF is often associated with complications other than lung disease such as CF-related diabetes (CFRD), increased risk for venous thrombosis and poor bone health [3]. There may be concerns that hormonal contraception may impact these complications. Additionally, there are concerns that malabsorption or altered drug metabolism in CF patients might impact effectiveness of some contraceptive methods. A recent review on contraception for women with CF found that while evidence on safety and efficacy was limited, most women with CF using contraception reported use of oral contraceptives (OCs) and condoms, with limited use of longer-acting, reversible methods [4]. Currently, there are no recommendations for contraceptive use by women with CF in the US Medical Eligibility Criteria for Contraceptive Use (US MEC) [5]. The objective of this review is to evaluate evidence on the safety and effectiveness of contraceptive methods among women with CF to add guidance for the use of contraceptive methods by women with CF to the US MEC.

2. Materials and methods

We conducted this systematic review according to Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines [6]. Our key question was whether women with CF who use various methods of contraception are at increased risk for adverse outcomes compared with women using other methods or no method of contraception. Outcomes of interest included measures of disease severity, diabetes-related outcomes, bone health and thrombosis, as well as indicators of effectiveness (e.g., pregnancy, pharmacokinetics). We searched the MEDLINE database for peer-reviewed articles published in any language from database inception through October 2015 concerning the safety of using any contraceptive method in women diagnosed with CF using the following search strategy:

“Contraceptives, Oral, Combined”[Mesh] OR “Contraceptives, Oral”[Mesh] OR “Contraceptives, Oral, hormonal”[Mesh] OR “Contraceptives, Oral, Combined” [Pharmacological Action]) OR (contracept* AND (oral OR pill OR tablet)) OR ((combined hormonal) OR (combined oral) AND contracept*) OR (contracept* AND (ring OR patch)) OR “ortho evra” OR NuvaRing OR (progestin* OR progestins[MeSH] OR Progesterone[MeSH] OR progesterone OR progestogen* OR progestagen* OR “Levonorgestrel”[Mesh] OR Levonorgestrel OR “Norgestrel”[Mesh] OR norgestrel OR etonogestrel AND contracept*) OR dmpa OR

“depot medroxyprogesterone” OR “depo provera” OR “net en” OR “norethisterone enanthate” OR “norethindrone enanthate” OR (contracept* AND (inject* OR implant)) OR ((levonorgestrel OR etonogestrel) AND implant) OR implanon OR nexplanon OR jadelle OR norplant OR uniplant OR sino-implant OR (levonorgestrel-releasing two-rod implant) OR “Intrauterine Devices”[Mesh] OR “Intrauterine Devices, Copper”[Mesh] OR “Intrauterine Devices, Medicated”[Mesh] OR ((intrauterine OR intra-uterine) AND (device OR system OR contracept*)) OR IUD OR IUCD OR IUS OR mirena OR Skyla OR paragard OR “Copper T380” OR CuT380 OR “Copper T380a” OR “Cu T380a”) NOT (“Animals”[Mesh] NOT “Humans”[Mesh]) AND ((cystic fibrosis[MeSH Terms]) OR “cystic fibrosis”).

Additionally, we hand searched reference lists from articles identified by the search and key review articles to identify any additional articles.

2.1. Study selection

We reviewed titles as well as abstracts to identify studies investigating the safety or effectiveness of using any contraceptive method among women diagnosed with CF. We included studies that examined health outcomes or indicators of contraceptive effectiveness among women diagnosed with CF initiating or continuing a contraceptive method. We excluded studies in which sampling was based on observed outcomes, and included all other study designs.

2.2. Study quality assessment

The evidence was summarized and systematically assessed. The quality of individual pieces of evidence was assessed using the United States Preventive Services Task Force grading system [7], with the exception of pharmacokinetic studies, for which there is no formal grading system.

2.3. Data synthesis

We did not compute summary measures of association due to heterogeneity across the included studies with respect to the outcomes reported and study design.

3. Results

The search strategy identified 37 articles. After reviewing the titles and abstracts of these articles, as well as the full articles when necessary, six articles met our inclusion criteria [8–13] and an additional article was identified examining contraceptive use among women, most with CF, after undergoing lung transplantation [14] (Table 1). Of the seven included articles, four examined measures of disease severity or other CF-related health outcomes and four, including one that also examined disease severity, examined measures of effectiveness (three reported on pregnancies and one was a pharmacokinetic study).

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