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Legal Case Study Of Severe IVF Incidents Worldwide: Causes, Consequences, And High Emotional, Financial, And Reputational Costs To Patients And Providers

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Abstract

OBJECTIVE: To determine the causes of lawsuits against ART/IVF providers and ways to prevent them.

DESIGN: Detailed descriptive analysis.

MATERIALS & METHODS: The Lexis Nexis, Westlaw, Bloomberg Law, and CaseLaw databases, newspaper and magazine articles, legal reviews, journals, and online publications were used for U.S. IVF incidents. For international cases, HFEA reports, and industry and online publications were queried. The search was not time restrained.

RESULTS: One hundred eighty-four IVF incidents (89.7% U.S., 3.3% U.K., 7.0% other), excluding large-scale tank and alarm failures and blackouts, which affected 264 people (86.0%, 3.8%, 10.2%) and 225 specimens (88.8%, 3.1%, 8.1%), resulting in 59 lawsuits (71.2%, 10.2%, 18.6%) were identified worldwide, and categorized by error types. Specimen mix-ups were the most prevalent type (91.0%). Meanwhile, the nine failed storage and alarm incidents caused most damage, affecting >1800 patients and >8100 specimens, and resulting in 181 initial lawsuits.

CONCLUSIONS: Overreliance on manual protocols, irregular/skipped audits, and human error led to IVF incidents reviewed. Damaged, destroyed, or lost embryos and embryo transfer to the wrong recipient have lifelong devastating effects on patients, for many of whom IVF was their last chance for parenthood because of cancer treatment, infertility, and/or age. Moreover, embryo mix-ups led to custody disputes over the newborn child(ren), as in Manukyan v. CHA Health Systems, and loss of identity in children and parents in sperm mix-up cases. U.S. babies born to embryo mix-ups are reunited with their genetic parents, following the legal precedent of Perry-Rogers v. Fasano. In many countries, however, the law protects birth parents. Most lawsuits are dismissed or settled because of outdated/missing laws concerning IVF procedures, reproductive specimens, health insurance, and patient bill of rights, and absent/relaxed regulation. Hence, we can only make educated estimates about the true scope of the issue and its financial cost to ART/IVF providers, which might range from thousands to millions of USD. Lawsuits also come at a great reputational cost for patients and providers, so the latter might benefit from embracing automation, robotics, and AI as a new standard of care in their practice and to avoid lawsuits.

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Rethinking Follicular Maturation: The Incorporation of Luteal Phase Stimulation In IVf Patients With Diminished Ovarian Reserve

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Abstract

OBJECTIVE: Studies suggest that a single ovarian cycle actually consists of several "waves" of follicular maturation. Therefore, the study aimed to optimize ovarian stimulation through the utilization of both follicular and luteal phase stimulation in IVF patients with diminished ovarian reserve (DOR).

DESIGN: Chart review of patients with a diagnosis of DOR was conducted at a multisite fertility practice in the United States. DOR was defined by pre-stimulation AMH level < 1 ng/ml.Patients underwent either DuoStim or Microdose Flare (MDF) protocol. DuoStim protocol consisted of follicular phase stimulation (FPS) by antagonist stimulation protocol, hCG trigger and oocyte retrieval, immediately followed by microdose leuprolide flare with recombinant FSH, hCG trigger, and oocyte retrieval. MDF protocol consisted of one ovarian stimulation cycle with microdose leuprolide and recombinant FSH with hCG trigger, and oocyte retrieval.

MATERIALS & METHODS: Outcomes were quantified as total number of oocytes retrieved, fertilization rate, and total number of embryos frozen per cycle. Outcomes of three cycle types (DuoStim FPS, DuoStim LPS, and MDF cycle) were statistically compared via one-way ANOVA. Unpaired t-test then compared the same outcome parameters between complete DuoStim cycles (FPS + LPS) and MDF cycles. Statistical analyses were performed using Graph Pad, LLC.

RESULTS: Statistical analysis suggested no significant difference in outcome parameters between DuoStim FPS, DuoStim LPS, and MDF groups (p=0.29, p=0.62, p=0.1; see Table 1). There was no significant difference in outcome parameters between a complete DuoStim cycle (FPS + LPS) and MDF cycle (p=0.12, 0.71, 0.74; see table 1). Of note, there was no significant difference in the outcome parameters between DuoStim FPS and DuoStim LPS (p=0.21, 0.22, 0.78; see table 1).

CONCLUSIONS: This study compared cycle outcomes in DOR patients who underwent IVF with DuoStim and MDF protocols. Whereas trends indicated that DuoStim resulted in a greater number of oocytes retrieved than MDF, this trend was statistically insignificant. Further, there was no significant difference in fertilization rate or number of embryos frozen between the two groups. These preliminary results suggest that DuoStim cycles, which can be costly, may not improve cycle outcomes in patients with DOR.

SUPPORT: None.

	Oocytes Retrieved	Fertilization Rate	Embryos Frozen
DuoStim FPS	4.4	0.45	0.40
DuoStim LPS	5.5	0.33	0.60
DuoStim Total (FPS+LPS)	9.70	0.38	0.90
MDF	6.82	0.42	1.08

(Table 1)

Mean number of oocytes retrieved, mean fertilization rate, and mean number of embryos frozen in DuoStim FPS, DuoStim LPS, DuoStim Total (FPS+LPS), and MDF cycles (p-values as noted in Results section).