ANDROLOGY

Impact of prednisone on vasectomy reversal outcomes (iPRED study): results from a randomized, controlled clinical trial

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Objective: To evaluate the safety and efficacy of prednisone on pregnancy rates and semen concentrations at 1 year after vasectomy reversal.
Design: Randomized, controlled trial (NCT04788823).
Setting: Single medical center specializing in vasectomy reversals.
Patient(s): Men undergoing vasectomy reversal.
Intervention(s): Participants were randomly assigned 1:1:1:1 to Control (no prednisone), Pred High (20 mg prednisone taper, every other month × 3 months), Pred PRN (20 mg prednisone taper × 3 courses maximum if sperm counts were declining or 0), and Pred Low (5 mg/d, every other week × 6 months). Note that Pred High and Pred PRN were stopped prematurely due to interim findings demonstrating lower pregnancy rates.
Main Outcome Measure(s): Pregnancy rates, semen concentrations, and adverse events. The current study reports outcomes at 1 year.
Result(s): A total of 75 men were enrolled, with 1-year data available in 73 (Control, n = 25; Pred High, n = 14; Pred PRN, n = 11; and Pred Low, n = 23). Baseline factors were similar among cohorts. Pregnancy rates at 12 months were higher in Controls (65%) and Pred Low (67%) compared with Pred High (17%) and Pred PRN (38%). Overall patency at 12 months (sperm at any point) was 99%, with no statistically significant differences noted between groups for patency, median concentrations by month (range, 3–42), or overall median concentrations (median of medians range, 5–16).
Conclusion(s): High-dose (20 mg) prednisone results in decreased pregnancy rates after vasectomy reversal, an effect which is independent of sperm concentration, dose dependent, and persists for months after discontinuation. Prednisone doses (ranging from 5 to 20 mg) do not impact sperm concentrations.
Clinical Trial Registration Number: NCT04788823 (https://clinicaltrials.gov/study/NCT04788823?term=NCT04788823&rank=1).
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Key Words: Vasovasostomy, vasoepididymostomy, steroid, assisted techniques

The role for corticosteroids in men undergoing vasectomy reversals has been a debatable topic since the drugs were first identified. As early as 1957, experiments were conducted in dogs to determine if cortisone could potentially improve outcomes and reduce anastomotic strictures (1). It was not until 1980, however, when the use of prednisone postvasectomy reversal was first documented (2). In their study of 40 men, Urquhart-Hay (2) treated men with either prednisone (40 mg daily) × 6 weeks vs. standard treatment. They reported higher overall pregnancy rates (55 vs. 45%) and return of sperm (95% vs. 70%), although multiple details were not reported including partner factors, follow-up period, or statistical analyses, among others. The technique also included use of a suture stent (removed 8–10 days later) and did not incorporate an operating microscope.

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Attestation statements: The subjects in this trial have not concomitantly been involved in other randomized trials; data regarding any of the subjects in the study has not been previously published; data will be made available to the editors of the journal prepublication and/or postpublication for review or query on request. The appropriate checklist for this study design was followed (consolidated standards of reporting trials).
Data sharing statements: Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices) will be shared, along with the study protocol. The data will be available beginning 9 months and ending 36 months after completion of the publication. The data may be shared with investigators whose proposed use of the data has been approved by an independent review board which has been identified for this purpose. The data will be made available for meta-analyses or similar studies. Proposals may be submitted up to 36 months after article publication.
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Later studies began reporting on the potential role for prednisone in cases of documented positive anti-sperm antibodies (3, 4). These studies also exhibited significant limitations, including small sample sizes, varying populations studied, lack of microsurgical techniques, mixed male and female fertility factors, and minimal data reporting. Additionally, the use of anti-sperm antibody testing has since fallen out of favor and is no longer considered appropriate contemporary management (5).

More recently, there has been renewed interest in the literature on the use of prednisone to address delayed vasal stenosis and anastomotic strictures. A 2020 retrospective study reported on outcomes of 89 men who received prednisone tapers (20 mg × 2 weeks, 10 mg × 2 weeks) if they experienced declining counts or 0 sperm postoperatively (6). Results demonstrated a mean increase in sperm concentration of 10.5 million/mL overall, with men who had counts >0 found to be more likely to respond. A second study of eight men with a ≥50% decrease in sperm concentration between tests reported improvements in 100% of individuals (7). However, both of these studies had several notable limitations, including an absence of pregnancy data, non-controlled testing frequencies, and lack of prospective Control comparisons.

Given the potential importance of this treatment for men undergoing vasectomy reversal, we sought to perform a randomized, controlled trial to evaluate the safety and efficacy of varying protocols of prednisone postoperatively. We hypothesized that the use of prednisone would improve sperm concentrations, increase pregnancy rates, and reduce long-term rates of anastomotic stenosis.

MATERIALS AND METHODS

Study design and cohort

After institutional review board approval, a randomized, controlled clinical trial (NCT04788823) was performed beginning in 2021 of men undergoing first time vasectomy reversal at a single, high-volume reversal center. Inclusion criteria were the need for a current sexual partner (age <36 with no infertility factors to limit the impact of female subfertility), the intent to achieve a pregnancy as soon as possible, age 18–65, and a history of prior paternity. Exclusion criteria were any current use of corticosteroids or relative contraindications to their use (diabetes, hypertension, and systemic fungal infections), renal insufficiency, testosterone use within 1 year of reversal, prior chemotherapy, solitary testicle, or use of hormonal birth Control (female partner) within the past 3 months.

The primary outcomes were differences in pregnancy rates, semen concentrations, and adverse events between cohorts at 3 years, whereas secondary outcomes were the same measures at 1 year. This study is reporting outcomes at 1 year.

Randomization was performed using predefined tables that were created by the research team before study initiation using random number generators. A total of nine separate tables were made, with <5 years, 5–12 years, and >12 years because vasectomy used as top-level criteria, followed by intraoperative vasovasostomy (VV)/VV vs. VV/epididymovasostomy (EV) vs. EV/EV selected as substrata within the different groupings. In this manner, every group would be represented at least once for every four men who would be enrolled under a particular grouping. This was done to ensure that factors which may skew outcomes toward one particular cohort were controlled as much as possible.

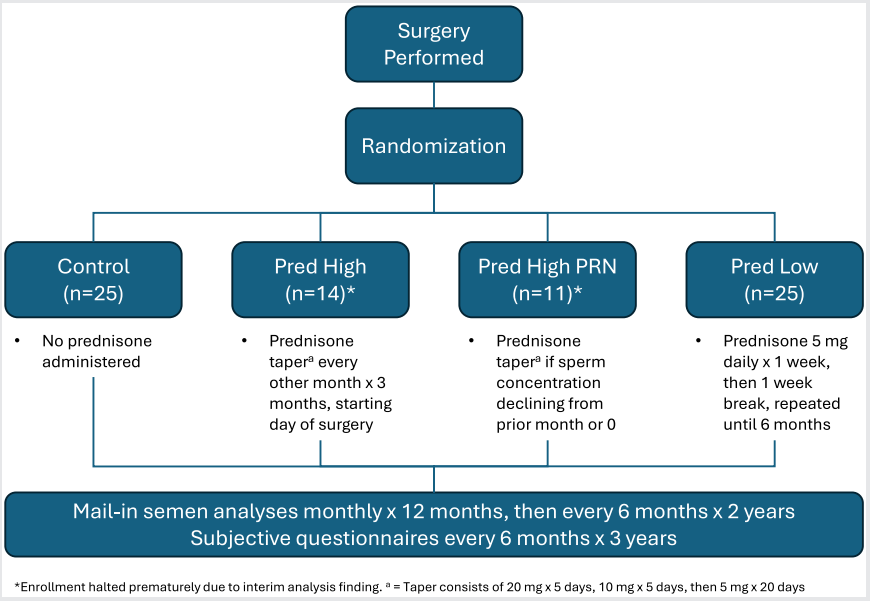
A total of 100 men were planned for randomization 1:1:1:1 into four groups: Control—no postoperative use of prednisone; Pred High—prednisone taper (20 mg × 5 days, 10 mg × 5 days, 5 mg × 20 days) beginning immediately postoperatively and then continuing every other month for three full courses; Pred PRN—prednisone taper postoperatively if sperm counts were declining from prior month or if 0, with up to three courses maximum; and Pred Low–prednisone 5 mg/day × 1 week, then 1 week break, continued × 6 months beginning immediately postoperatively. The study was open label in design, with no attempts made to mask the therapy received to either the patient or investigator. Figure 1 depicts graphical representation of study groupings. The dosages for groups 2 and 3 were selected based on previously published regimen, whereas group 4 was arbitrarily selected to represent a low-dose, prolonged regimen that would provide treatment for a similar timeline to the other groups (ie, approximately 6 months). The decision to limit treatment to a maximum of three taper courses (750 mg total) or a maximum of 6 months of alternating 5 mg dosages (420 mg total) was arbitrarily selected, as we felt that this would provide a sufficient dosage to determine if the treatments were having an effect on pregnancy, concentrations, and patency rates long-term without exposing patients to excessive dosages of glucocorticoids.

Assessments

Assessments consisted of subjective questionnaires (every 6 months × 3 years) and mail-in semen kits (monthly × 12 months, then every 6 months for 24 additional months). Subjective questionnaires included nonvalidated questions on whether the couple was continuing to try to achieve a pregnancy, ongoing partnership, interim use of assisted reproductive techniques or contraceptives, interim pregnancies, births and miscarriages (including dates), and questions on subjective stress relating to fertility for the patient and partner. The number of prednisone cycles administered was recorded as well as drug discontinuation or any drug-related adverse events.

For assessment of semen concentration, mail-in kits were used to ship specimen to our clinical laboratory improvement amendments-certified laboratory to manually evaluate semen concentration. No other measures were assessed, such as motility/morphology given the mail-in nature and based on prior publications (and our internal data) demonstrating a consistent, positive-predictive value of concentration alone (8, 9). This was also selected to ensure consistency of reporting, given our prior experience with variable accuracies from outside semen analyses, to facilitate compliance, and given the non-feasibility of enrolling only local patients who met criteria, would be willing to enroll, and could provide monthly samples for an extended period. Patients were counseled to abstain from ejaculating for 2–5 days before providing the sample.

FIGURE 1



Study timeline demonstrating allocation of participants into the randomized groupings.

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Statistical analyses

Data were reported with medians/interquartile ranges. For normally distributed, continuous data, analysis of variance, and Student's t tests were performed, whereas Wilcoxon testing was performed for skewed data. Categorical variables were assessed using χ^2 analyses, with likelihood ratios used for categories with fewer than five observations. Missing data points were not imputed or carried forward. All data were analyzed using JMP (SAS Institute, Cary, NC), with $P<.05$ considered significant.

A power analysis for sperm concentration was performed assuming a sample size of 80 and indicated 80% power to identify differences of approximately 23 million/mL among groups (standard deviation, 26). For pregnancy, using an estimated pregnancy rate of 30%, this study was powered to detect a 24% difference between groups. Given the early termination of groups 2 and 3, a post hoc power analysis was performed. Results demonstrated the ability to detect a 13.3 million/mL difference between groups with 90% power (actual standard deviation, 13) and confirmed >90% power to detect the differences in pregnancy rates at 6 months between Pred High and Pred Low/Control, confirming validity of results.

RESULTS

A total of 75 men were randomly assigned: Control (n = 25), Pred High (n = 14), Pred High PRN (n = 11), and Pred Low (n = 25). Although the original intent was to randomly assign 25 men to each arm, an interim analysis demonstrated clearly lower pregnancy rates in the Pred High and Pred High PRN groups, which resulted in discontinuation of enrollment into those two arms. Two men in the Pred Low group did not return any surveys or semen analyses during the 12 months postoperatively and were not included in 6- and 12-month outcomes reporting.

Baseline factors were similar among all groups (Table 1). Specifically, men had similar ages, durations since vasectomy, types of procedure performed (VV vs. EV), prior fertility, and partner fertility.

Results from semen testing demonstrated no statistical differences at any time point, including when data were analyzed among groups or if the prednisone groups were combined. Patency rates (defined as sperm at any point postoperatively) were also similar among all cohorts (overall patency 99% or 72/73). Pregnancy results were notably different among cohorts at both the 6- and 12-month time points. Specifically, men who received the higher-dose prednisone (either scheduled or PRN) had significantly lower pregnancy rates. The results also appeared to be dose dependent, with PRN men experiencing higher pregnancy rates compared with Pred High men but lower than non-high-dose men (Control and Pred Low). Semen results and pregnancy outcomes by time point are reported in Table 2 and shown in Figure 2 and Supplemental Figure 1 (available online).

Adverse events were low and minor/self-limited. A total of four men discontinued prednisone (of 48 who received it), with the reasons for discontinuing being depressed mood, nausea, and weight gain. Regarding subjective reporting of stress related to infertility, both men and partners in the high-dose arms reported significantly higher rates of stress (~2–3 points higher on 1–10 scale), $P=.01$ and .03,

TABLE 1

Demographics by study group.

Variable[a]	Control (n = 25)	Pred High (n = 14)	Pred High PRN (n = 11)	Pred Low (n = 25)
Patient demographics, clinical, and operative factors				
Age	38 (2)	39 (2)	38 (2)	38 (2)
Years since vasectomy, median (IQR)	4 (3–7)	4 (4–11)	6 (2–12)	5 (3–8)
Surgical procedure (%)				
VV/VV	80	64	91	88
VV/EV	20	21	9	12
EV/EV	0	14	0	0
Pregnancies achieved by male previously	2 (2)	3 (1)	3 (1)	3 (2)
Pregnancies achieved by female previously	2 (0)	1 (0)	1 (0)	1 (0)
Pregnancies achieved together previously (if applicable)	1 (0)	1 (0)	1 (0)	1 (0)
Use of prednisone cycles	NA	100	82	NA
Percent of men using at least one cycle		3	1	
Median number of cycles				
Partner factors				
Age	32 (1)	31 (1)	29 (1)	30 (1)
Prior fertility evaluation (% yes)	4	15	9	0
Last use of contraceptives (mo)	61 (9)	48 (14)	49 (15)	57 (11)

Note: EV = epididymovasostomy; IQR = interquartile range; VV = vasovasostomy.

[a] All variables reported as mean (standard deviation) unless otherwise noted; note that responses to some items may be missing such that the total number varies by item.

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respectively. Adverse events and subjective reporting are shown in Supplemental Table 1, available online.

DISCUSSION

To our knowledge, this study is the first randomized, controlled trial ever performed in men undergoing a vasectomy reversal and presents several notable findings. Arguably, the most significant finding observed is that men treated with higher-dose prednisone regimen experience significantly worse pregnancy outcomes, despite preserved semen parameters. Additionally, men treated with low-dose protocols do not appear to experience a higher rate of pregnancy compared with those who did not receive prednisone. These findings are clinically important given that the primary objective with a vasectomy reversal is to achieve a pregnancy and would suggest no role for prednisone at the doses/administration schedules studied up to 1-year postoperatively. At a minimum, the findings would strongly argue against the use of higher, "tapered" dose protocols.

The underlying etiology for the observed discrepancy between semen parameters and pregnancy as well as the lower pregnancy rates overall in men receiving high-dose prednisone is unclear, as this represents a new scientific finding. However, these results are consistent with clinical observations and may help to explain the long-recognized negative impact of physiologic stress on fertility. In both men and women, it has long been recognized that high levels of stress result in decreased overall fertility (10, 11). As physiologic stressors result in a release of endogenous glucocorticoids, it is possible that the glucocorticoids themselves may be resulting in the impaired fertility. Until now, the effect of exogenous glucocorticoids on male fertility, and specifically on pregnancy outcomes, has not been thoroughly examined. Results from this study demonstrate a dose dependent, negative impact of glucocorticoids on pregnancy, despite preserved semen concentrations. Additionally, findings indicate a prolonged effect of these treatments, given that men in the Pred High arm continued to experience difficulties in achieving a pregnancy out to 12 months, despite stopping the medication at 5 months postoperatively. This would suggest that glucocorticoids impair fertility via mechanisms other than sperm production itself and for prolonged periods. This is important clinically, because semen analyses are often the most widely used method of objectively testing male reproductive potential and may inadvertently reassure patients who are requiring these regimens. Findings may also suggest a potential mechanism by which physiologic stressors result in increased glucocorticoid release and subsequently result in impairments in male fertility.

The impact of glucocorticoids on testicular function and fertility is not well studied. Notably, men with syndromes such as congenital adrenal hyperplasia (glucocorticoid deficiency) experience reduced sperm production, a condition which may be ameliorated through direct supplementation of exogenous glucocorticoids (12). Similarly, recent histologic data by Stepanov et al. (13) have confirmed the presence of glucocorticoid receptors within in the testicular peritubular

TABLE 2

Sperm concentrations and pregnancy outcomes by group during first 12 months postoperatively.

Variable[a]	Control (n =25)	Pred High (n = 14)	Pred High PRN (n = 11)	Pred Low (n = 23)	*P*
Sperm outcomes					
Patency (>0 sperm at any point) (%)	100	92	100	100	.3
Concentration, median of medians (IQR)	10 (5–17)	8 (1–32)	5 (3–11)	16 (7–27)	.14
Concentration (1 mo)	7 (5–16)	7 (1–37)	6 (1–9)	11 (5–24)	.4
Concentration (2 mo)	13 (1–27)	10 (3–15)	13 (2–16)	10 (6–24)	.7
Concentration (3 mo)	10 (5–24)	13 (0–24)	3 (1–15)	9 (2–29)	.9
Concentration (4 mo)	10 (3–22)	17 (9–51)	3 (0–65)	18 (12–67)	.2
Concentration (5 mo)	16 (3–25)	11 (0–26)	4 (2–31)	20 (9–29)	.5
Concentration (6 mo)	11 (3–32)	8 (1–24)	13 (2–20)	16 (8–19)	.9
Concentration (7 mo)	14 (8–23)	30 (1–33)	39 (0–78)	9 (4–23)	.9
Concentration (8 mo)	14 (8–23)	3 (0–16)	3 (0–79)	13 (5–30)	.5
Concentration (9 mo)	19 (4–48)	8 (3–62)	39 (0–78)	8 (3–24)	>.9
Concentration (10 mo)	6 (0–18)	6 (1–36)	42 (3–110)	42 (9–56)	.3
Concentration (11 mo)	10 (6–12)	19 (7–38)	5 (0–69)	14 (3–20)	.7
Concentration (12 mo)	9 (3–30)	7 (0–37)	8 (2–107)	19 (4–32)	.8
Pregnancy outcomes					
0–6 mo postoperatively, spontaneous	69	10	38	60	.02[b]
0–12 mo postoperatively, spontaneous	65	17	38	67	.02[b]
Miscarriages (%)	13	0	13	19	.3
IVF, IUI, or redo reversal (n)	0	0	2 (not included in pregnancies above)[c]	0	.05
Stopped trying to achieve pregnancy (excludes those who already achieved pregnancy)	16	11	0	33	.39

Note: IQR = interquartile range; IUI = intrauterine insemination; IVF = in vitro fertilization.

[a] All variables reported as mean (standard deviation) unless otherwise noted.

[b] Effect sizes (η^2) for 0 to 6 and 0 to 12 month pregnancies were 0.06 (η^2) for both, indicating a medium effect size; note that responses to some items may be missing such that the total denominator varies by item.

[c] Note that one of the two couples who did IVF had a semen concentration of 16.3 million/mL at 2 months and subsequently declined to 0 at 4 months and remained 0 through 12 months. The second individual has persistent concentrations >15 million/mL.

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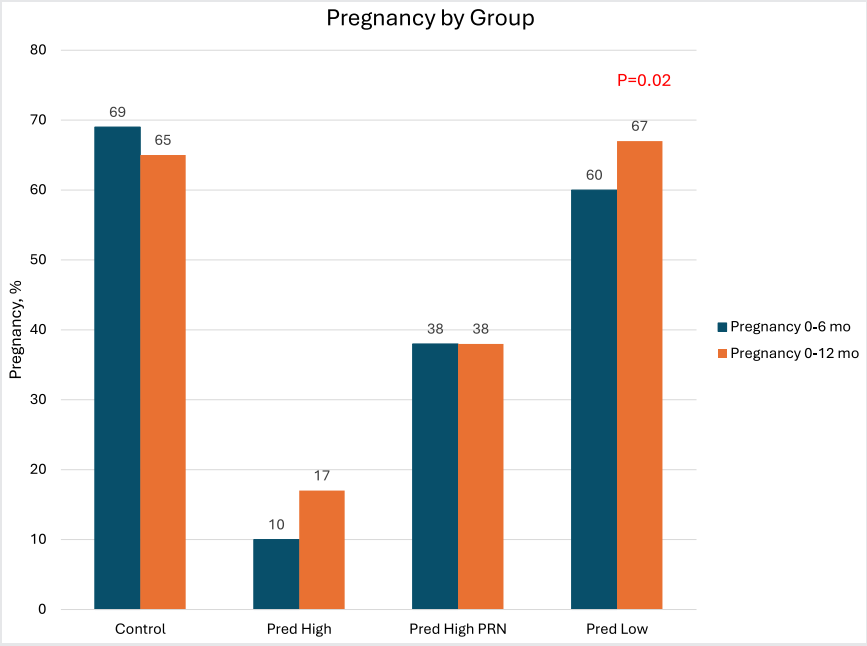
cells (located between the seminiferous tubules and interstitial regions). In their evaluation of the effects of dexamethasone on the testicles, the investigators demonstrated significant reductions in numerous cytokines, cellular proteins, secretomal proteins, and glucocorticoid receptors, with effects occurring in a time-dependent manner. Several of the proteins were recognized to play important roles in maintaining the extracellular matrix and basement membrane, among others. These data provide histologic evidence to further support our study findings and hypothesis that excessive, exogenous glucocorticoids may be a mechanism leading to impaired fertility. Specifically, it appears that tight glucocorticoid regulation may be essential to maintaining optimal fertility in men, and over-supplementation and/or exogenous replacement may have a detrimental effect on function.

The current data also fail to support clear benefits of prednisone on improving semen parameters or in preserving vasal patency out to 1 year. These observations are important, as these are typically the most highly cited reasons for utilizing prednisone postoperatively. Two publications have reported improved semen parameters when prednisone was used postoperatively in men with declining counts (n = 89 and n = 8), whereas one study evaluated its efficacy in men postreversal with anti-sperm antibodies (unclear number of men/treatments applied) (4, 6, 7). Although these studies reported improvements in semen parameters (pregnancies not reported), they all represented retrospective series and had very high risks of bias. Specifically, data presented from this study highlight both the highly variable nature of semen analyses from one time point to the next and a general trend of increasing counts for the first 4–6 months, followed by a decline, and a subsequent increase (Fig. 1). Given that "rescue" prednisone courses are often prescribed for men with 0 sperm or declining counts, this biases treatment results in favor of achieving a subsequent increase (floor effect bias). As such, it tends to suggest that nearly any treatment administered in these men would be expected to demonstrate a potentially positive effect. It also highlights the importance of including Control groups in any such studies.

This study has several limitations including the overall sample size, first time surgery inclusion, single surgeon, and use only of couples with no female factors. Although the sample size is sufficient to identify larger differences between groups, it is inadequate to recognize smaller changes in semen concentration. Additionally, results are only reporting findings at 12 months, which may not reflect

FIGURE 2



Pregnancy outcomes at 6 and 12 months by study group.

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future findings. It is notable that the only two men who underwent EV/EV were randomly assigned to the Pred High group using the predefined randomization tables. One of the men went on to achieve a return of sperm (max 15 million/mL), whereas the other failed to return any questionnaires (and thus did not factor into the results denominator). As such, this did not likely invalidate the findings of the high-dose group. Indeed, even if both had been counted as pregnancies, the overall 12-month rate would still only be 31%, less than half the Control and Pred Low arms. Despite these limitations, the study has several notable strengths, including its randomized nature, use of varying dosages and protocols for prednisone, limited exclusion criteria (essentially all-comer male population for first time reversal), single-laboratory analysis of results, and use of multiple sequential semen analyses.

CONCLUSION

The use of high-dose (20 mg taper) prednisone administered as either a scheduled dose or PRN results in significantly worsened pregnancy outcomes, despite maintained sperm concentrations. The impact appears to be dose dependent and persists for at least several months after drug discontinuation. As such, the data (at 1 year) would argue against the use of high-dose (20 mg taper) prednisone as a routine or salvage therapy in men postreversal. The use of prednisone (5 mg) (week on, week off × 6 months) does not appear to impact semen parameters or pregnancy outcomes compared with Controls.

CRediT Authorship Contribution Statement

Landon Trost: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Writing – original draft, Writing – review & editing. Sevann Helo: Formal analysis, Methodology, Writing – review & editing. Klinton Brearton: Data curation, Investigation, Methodology, Writing – review & editing. Riley Warner: Data curation, Investigation, Methodology, Writing – review & editing. Matthew Ziegelmann: Formal analysis, Methodology, Writing – review & editing. Tobias Kohler: Formal analysis, Methodology, Writing – review & editing. Joshua Savage: Data curation, Investigation, Methodology, Writing – review & editing.

Declaration of Interests

L.T. has nothing to disclose. S.H. has nothing to disclose. K.B. has nothing to disclose. R.W. has nothing to disclose. M.Z. has nothing to disclose. T.K. has nothing to disclose. J.S. has nothing to disclose.

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