

Effects of BabyDance Lubricant on Sperm Parameters

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ABSTRACT

Background: Semen analysis is a common test conducted for diagnosing the cause of male infertility, so using an innocuous lubricant can be beneficial to reduce the semen collection difficulties. **Aims:** In this study, the effects of BabyDance™ lubricant gel, a paraben-free lubricant, on sperm parameters were investigated. **Study Setting and Design:** It was a prospective study and a total of 45 individuals were enrolled. **Materials and Methods:** First, the semen samples of 20 patients referred to Royan Research Institute were incubated with different concentrations of gel, and subsequently, the sperm motility and vitality were evaluated. In the second phase, 25 individuals who had a spermogram test were asked to apply the gel in the new semen examination. **Statistical Analysis:** Obtained data were statistically analysed using SPSS software. **Results:** The results of the *in vitro* phase revealed that this gel does not affect the pH, sample colour, viability, total motility and progressive and non-progressive motility of spermatozoa at any concentration. The second phase results also represented no difference in spermatozoal characteristics with and without gel use. Moreover, 100% of the participants in the second phase were satisfied with the gel and recommended that to other patients. **Conclusion:** It was concluded that this gel can be considered a harmless product to sperm and can be a beneficial option for clients referring to infertility centres that facilitate the semen collection process.

KEYWORDS: BabyDance lubricant gel, semen analysis, sperm parameters

INTRODUCTION

Infertility is a growing problem that affects approximately 15% of couples of childbearing age.^[1] One-third of infertility cases are correlated with malefactors, one-third attributed to female factors and, in one-third of couples, there is no identifiable cause, also known as unexplained infertility.^[2]

As sperm abnormalities are the major cause accountable for male infertility, sperm analysis is an important test to reveal the fertilisation potential of sperm. Semen analysis is the first test requested by doctors, to assess the fecundity status of men after taking a history and examination. Routine semen analysis provides useful information about the number (count), motility, morphology of the male gamete and other factors that can affect the ability of sperm to fertilise the egg.^[3] For a variety of reasons including stress, collecting the

semen sample could be irritating for some couples referred to medical centres for diagnostic or therapeutic infertility-related tests. This stress can lead to difficulty or even inability to collect semen samples through masturbation, especially in treatment centres, where it is not common for a male to request a lubricant to facilitate the sample collection process.^[4,5] Hence, in these conditions, using a lubricant that is harmless to spermatozoa would be helpful. Although common lubricants are often labelled ‘non-lethal to sperm’, this does not mean that these products do not impair sperm function and have no adverse impact on its parameters, whether in cases the couples trying to conceive or in

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diagnostic and therapeutic approaches in infertility treatment centres.^[6]

Moreover, vaginal lubricants are used worldwide to reduce vagina dryness and pain during sexual intercourse. Specifically, women who are trying to conceive may experience increased vaginal dryness due to the stress and some medicine associated with intercourse during ovulation.^[7,8] In fact, 25% of these women reported using a lubricant ‘always’ during intercourse.^[8]

Over the decades, many studies have consistently demonstrated the spermicidal effect of common lubricants, even lubricants that are free of sperm-killing agents such as Astroglide.^[6,9] Besides, saliva has even been reported to induce damaging impacts on spermatozoa.^[9,10] According to these investigations, a few minutes of sperm direct contact with these lubricants or saliva results in many disorders in sperm motility and viability. To date, the destructive effects of these products on sperm function and even fertility during sexual intercourse for natural pregnancy have been proved.^[11]

The present study aimed to investigate the effect of using a lubricant gel under the brand name BabyDance Fertility Lubricant on sperm parameters in the laboratory and also during the semen sample collection of men referred to Royan Research Institute.

MATERIALS AND METHODS

Study population and semen collection

A total of 45 individuals participated in this prospective study. The study was performed in two separate phases: *in vitro* and *in vivo*. In the first phase (*in vitro*), semen samples from 20 normozoospermic individuals were collected, and in the second phase (*in vivo*), 25 individuals with motile spermatozoa were recruited for further examinations. This study was conducted in accordance with the Helsinki Declaration and also by the Ethics Committee of Royan Institute for Reproductive Biomedicine (EC approval number: IR.ACECR.ROYAN.REC.1398.175). Each participant was informed about the study and gave written informed consent. No sample size calculation was performed.

BabyDance gel ingredients

BabyDance gel contains the following components: purified water, cetyl hydroxyethylcellulose, hypromellose, carbomer homopolymer Type B, sodium phosphate, potassium phosphate, sodium chloride, raspberry-derived xylose, sodium hydroxide, phenethyl alcohol, caprylyl glycol and *Salvia sclarea* (clary sage).

In vitro phase

After obtaining the informed consent, semen samples from 20 healthy normozoospermic men were collected by masturbation after a sexual abstinence of 2–3 days. After liquefaction at 37°C for 30 min, the semen samples were evaluated according to the World Health Organization criteria 2010. The desired concentrations of gel (1:2, 1:4 and 1:8 [v/v]) were adjusted in normal saline. The contents of each aliquot were thoroughly mixed and incubated for 30 min at 37°C. An untreated aliquot of sperm suspension served as the control. The total and progressive sperm motility was evaluated by computer-assisted sperm analysis. Afterwards, Eosin-Nigrosin staining was performed to identify live motile sperm from dead ones. For this purpose, an equal volume of the semen sample and Eosin-Nigrosin dye (50 µl) were mixed together in a test tube, and after 5–10 min, 20 µl of each specimen was taken for smear preparation. The dead sperms turned to a dark pink because of plasma membrane defects, whereas live spermatozoa appeared in white.

In vivo phase

At this stage, informed consent was obtained from 25 participants referred to the research institute. Each of the subjects was given a 4-cc volume tube of lubricant gel to use for semen collection. All of the participants had at least a semen test in the past month.

Qualitative questionnaire

To assess the satisfaction level of users, a brief qualitative survey was carried out by distributing a question form and each of the participants was asked to complete the questionnaire regarding the use of gel during sample collection and their tendency for further use.

Statistical analysis

Data obtained from participants were analysed using SPSS software version 22 (SPSS 22.0; SPSS Inc., Chicago, IL) and the repeated measures test to evaluate the difference of the results before and after the intervention. $P < 0.05$ was considered statistically significant.

RESULTS

The results of the first phase

It was found that BabyDance gel does not change the pH and colour of semen samples. Examination of sperm motility demonstrated no significant changes in the amount of progressive sperm motility at concentrations of 1:2, 1:4 and 1:8 in comparison to the control group ($P = 0.067, 0.08$ and 0.824 , respectively). Furthermore, there was no statistically significant difference of non-progressive motility and total sperm motility between any of the studied concentrations.

As well, statistical analysis did not show a significant difference between any of the concentrations studied regarding the sperm viability, indicating that this gel has no detrimental influence on sperm viability [Figure 1].

Results of the gel application phase during sample collection

The results of the *in vivo* phase were consistent with the *in vitro* phase, and the gel had no impact on semen pH and viscosity. In addition, there were no differences in progressive motility ($P = 0.473$), non-progressive motility ($P = 0.740$) and total motility ($P = 0.782$) and also the mean of immotile spermatozoa ($P = 0.886$).

Besides, the comparison of information obtained from the first and second spermograms of patients represented that the use of gel did not affect sperm morphology and no significant difference was observed in this case ($P = 0.453$) [Figure 2].

Results of the survey and evaluation of the gel by the clients

In the second phase of this study, a survey and evaluation sheet was delivered to each client, and the answers to the questionnaire are summarised in Table 1. As it is shown, 84% of the clients stated that the amount of gel in the tube was appropriate and the remaining 16% found that the amount of gel was high. Furthermore, 80% of these people considered the slipperiness of the gel to be appropriate and another 20% announced that the slipperiness was very high.

Next, 60% of these clients rated the sampling process without using the gel as difficult, 28% as very difficult and 12% as easy. This statistic changed after using the gel, 52% said it was easy to sample with gel and 48% said it was very easy.

DISCUSSION

It is estimated that about one-third of infertility cases are

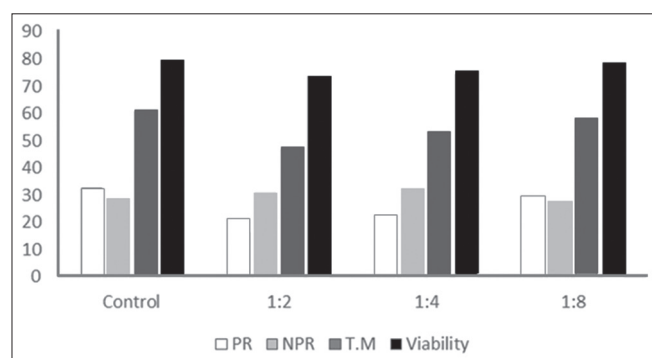


Figure 1: Statistical analysis of the first phase. No statistically significant decrease was observed in the semen parameters at different concentrations of the gel. PR = Progressive motility, NPR = Non-progressive motility, TM = Total motility

attributed to malefactors and sperm abnormalities are the most common reason for this condition; therefore, semen analysis is the cornerstone of the laboratory evaluation of the infertile male and helps to diagnose the severity of the malefactor.^[12]

Combining semen with water, saliva, gels and oils can be harmful to spermatozoa. The semen collection process could be bothering some clients for a variety of reasons, such as stress and the patient's, physical and mental condition, so the use of lubricant gels can be a potential solution to this problem, but these gels should not alter the semen parameters in the experiment.

Over the decades, many studies have consistently demonstrated the spermicidal effect of common lubricants, even lubricants that are free of sperm-killing agents such as Astroglide.^[6,9] All these studies have reported many disorders in sperm motility and viability, which occur after a few minutes of direct contact of sperm with these lubricants or saliva. The negative effects of these products are such that they affect sperm function and even fertility when used during sexual intercourse for natural conception.^[11]

In 2008, a team investigated the effect of Pre-Seed, FemGlide, Astroglide, Replens and K-Y Jelly lubricants

Table 1: Summarised information obtained from the questionnaires regarding the opinion of clients in using BabyDance lubricant gel

Question	Response (%)		
	High	Sufficient	Low
The amount of the gel supplied	4 (16)	21 (84)	0 (0)
Gel slipperiness	5 (20)	20 (80)	0 (0)
Question	Yes	No	
Tendency of gel application in the next referral	25 (100)	0 (0)	
Recommendation of gel use to other clients	25 (100)	0 (0)	
Question	Useful	Irritating	
Overall assessment of the gel use	25 (100)	0 (0)	

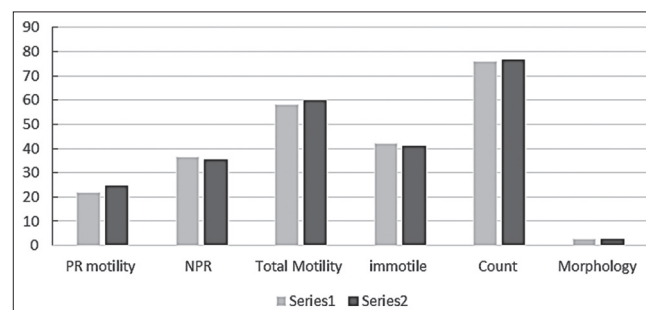


Figure 2: Statistical analysis results of the second phase. None of the semen parameters revealed a significant difference in the two series of spermogram assessments. PR = Progressive motility, NPR = Non-progressive motility

on sperm motility and chromosomal integrity. The results of this study demonstrated that amongst these common lubricants available, Pre-Seed does not reduce sperm motility and chromatin integrity.^[7]

In 2013, a study showed that an isotonic lubricant (Pre-Seed-INGfertility) had the least detrimental effect in sperm motility as well as chromatin integrity. This study also for the first time examined the level of satisfaction of individuals in using a particular type of lubricant, in which 73% of people preferred to use this isotonic lubricant for semen collection and 55% suggested its use for others.^[13]

In another study in 2014, the effect of 11 different lubricant gels on sperm motility and viability was examined *in vitro* and it was shown that amongst the gels used, only Pre-Seed gel did not have harmful and lethal effects on sperm.^[14]

In 2014, the effects of several different lubricant gels and several natural oils on sperm motility were investigated *in vitro* and it was shown that sesame oil and synthetic lubricants (other than Pre-Seed) cause decreased sperm motility and may reduce fertility chance. Pre-Seed, canola and baby oil had no destructive effect and can be considered sperm-friendly lubricants.^[15]

The present project aimed to analyse the importance of facilitating lubricant, BabyDance, for semen collection and its effect on semen parameters.

This lubricant is the first case that the manufacturer claim is paraben free and has no adverse effect on sperm function and quality. Here, unlike other studies that examined the effect of the studied gel at a concentration of 10%, the concentrations of 1:2 (50%), 1:4 (25%) and 1:8 (12.5%) of this gel were evaluated. To our knowledge, this study is the first that examined all the parameters that may be affected.

In the first step, different concentrations of the gel were incubated with samples of 20 patients referred to Royan Research Institute for 30 min, and the pH, colour, motility and viability of the sperm were measured before and after exposure to the gel. The results showed that this gel does not affect the pH and colour of the sample at any concentration. Furthermore, a similar result was obtained in the evaluation of sperm viability and it was found that this gel will not deteriorate sperm viability. Sperm motility analysis demonstrated no statistically significant changes in the progressive, non-progressive and total sperm motility at different concentrations of the gel.

In the next step, 25 patients who had undergone another spermogram test within a maximum of 1 month from

the date of referral were asked to use the gel. The parameters of pH, viscosity, motility and morphology of sperms were compared in two experiments, and the results of this study showed that the use of this gel did not change any of the above parameters and in other words confirmed the safety of using this facilitating lubricant in men with difficulties in preparing semen sample. In the second phase of the study, finding patients who had normal semen parameters with another semen analysis in the past month was difficult. On the other hand, convincing these patients to be part of the study and using the gel was also another matter of this project.

In addition to the informed consent form, a gel survey and evaluation form was given to each of the 25 individuals to answer questions after using the gel, if possible. All of these people considered the use of this gel as a useful and appropriate example and tended to apply it in future visits and all of them also recommended the use of the gel to other clients.

CONCLUSION

The presence of a lubricant gel approved by regulatory authorities has always been one of the concerns of some patients referred to male infertility centres for testing their semen sample; therefore, conducting detailed studies and evaluating the various gels available in the market can be a significant contribution to this group of patients. The results of this study showed that BabyDance Fertility Lubricant gel is harmless for sperm, and according to the opinion of people applied this gel, it can be a very suitable lubricant for infertility treatment centres. As this gel does not affect any of the semen parameters, the clients can go through the sampling process with more ease and ease. Furthermore, since this gel is innocuous for sperm, it can be proposed that using this gel during sexual intercourse in couples who desired to have children can also be helpful; however, further investigation on this gel is required to elucidate its effects in natural conception.

Data availability statement

The data sets in this study are available with the corresponding author upon reasonable request.

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Conflicts of interest

There are no conflicts of interest.

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