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The aim of this study was to evaluate the potential efficacy of each Dietary supplement (DS) proposed for male infertility and marketed in Italy, using an adapted version of the scoring system by the American Heart Association. In particular, the effect of any ingredients was evaluated according to semen alterations.

On the website of Italian ministry of health we found 23 supplements marketed for male infertility. We considered as eligible only randomized clinical trials (RCTs) evaluating substances included in DS marketed for male infertility. A formula allowed us to classify the expected efficacy of each DS, based on composition. Each DS was scored and included into three classes of expected efficacy: high, low and none.

Among 24 supplements, 3 (12,5%) fall in high, 9 (37,5%) in lower and 12 (50,0%) in no expected efficacy class. DS composition showed 36 substances, 18 with no literature on male fertility and 18 showing positive effect on sperm parameters, thus considered potentially active ingredients (PAI). All DS were mixtures of ingredients, containing from 2 to 17 different substances. Fifteen supplements (65.2%) contained at least 1 ingredient without evidence of efficacy and 21 formulations had PAI dosed below mED. Some PAI were associated to the improvement of specific sperm parameters.

DS were usually blends of many substances, that are frequently employed at negligible dose or without any evidence of efficacy on male reproduction. Some ingredients have been demonstrated to be effective on specific sperm parameters by RCTs. We report a list of ingredients with potential efficacy on specific sperm parameters, aimed to allow a tailored use of DS.

In the light of our findings we rise three final considerations: i) the Italian market of DS for male infertility offers products with potential efficacy in the improvement of sperm parameters but also many with uncertain effect; ii) the actual literature is poor of well-designed studies on PAI investigating their mechanisms of action and effective dose in different pathological conditions; iii) based on current literature, our study can help in the choice of DS and PAI that are more likely to be effective on specific sperm alterations.

Our critical analysis suggests a rational strategy for a tailored use of DS in male infertility.

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## **Reproductive Endocrinology**

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***Systematic review and critical analysis on dietary supplements for male infertility: from a blend of ingredients to a rationale strategy***

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