

The Stem Cell Market for the Treatment of Knee Osteoarthritis: A Patient Perspective

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INTRODUCTION:

The use of stem cell therapies for the treatment of various musculoskeletal conditions, especially knee osteoarthritis, is rapidly expanding, despite only low-level evidence to support its use. Centers offering these therapies are often marketing and charging patients out-of-pocket costs for such services. Therefore, the purpose of this study was to determine the current marketed: 1) prices, and 2) clinical efficacy of stem-cell therapies for knee osteoarthritis.

METHODS: This was a prospective cross-sectional study which queried 317 United States centers that offered direct-to-consumer stem cell therapies for musculoskeletal conditions. A total of 273 of 317 center were successfully contacted via phone or email, using a simulated 57-year old male patient with knee osteoarthritis (**Figure 1**). The contacted centers were consulted for information on same-day stem cell injections, and specifically asked questions focusing on two main themes: **1) Clinical efficacy** (“How well do they work?,” and “What effect do they have?”); and **2) Cost** (“What is the cost of the therapy for one knee?”). Centers generally reported the proportion of patients who had “good results” or “symptomatic improvement.”

RESULTS:

Marketed Prices: Of the 65 centers that provided pricing information for a same-day stem cell unilateral knee injection, the mean cost for each therapy was \$5,156, with prices ranging from \$1,150 to \$12,000 (**Table 1**). The standard deviation was \$2,446, with a margin of error of \$606 and a 95% CI (\$4550, \$5762). Out of the 65 centers, 14 centers charged < \$3,000; and 10 centers charged more than \$8,000 per injection.

Marketed Clinical Efficacy: Of the 36 centers that provided information on clinical efficacy (**Table 2**), the mean marketed clinical efficacy was 82.2% (range, 55% to 100%). The standard deviation was 9.6%, with a margin of error of 3.2% and a 95% CI (79.0, 85.5%). The distribution of the percentages reported by these clinics directly to consumers was aggregated, and shown as a histogram (**Figure 2**). Out of the 36 clinics, 10 claimed “90 to 100% efficacy,” 15 claimed “80 to 90% efficacy,” 10 claimed “70 to 80% efficacy,” and 1 claimed “55% or greater clinical efficacy.”

The geographical pricing distribution can be observed in the US map (**Figure 3**).

DISCUSSION AND CONCLUSION:

The use of stem cell therapies for the treatment of various musculoskeletal conditions, especially knee osteoarthritis, is rapidly expanding, despite there being only low-level evidence to support its use. The cost of these therapies averages about \$5,000 per injection, and centers claim that 80% of patients had “good results” or “symptomatic improvement.”

Cellular-based therapies, and their commercial development, should still be considered at the proof-of-concept stage due to potential unknown risks, minimal supporting evidence, changing policies, and being a highly dynamic sector with multiple explored therapeutic approaches. While some benefits have been reported, precise clinical indications have yet to be defined, and marketing claims should reflect this reality to patients. Furthermore, establishing an appropriate sustainable pricing and reimbursement for cell-based regenerative therapy will become a greater challenge. To date, the price for receiving these therapies is high, and is even sometimes greater than the costs for a total knee arthroplasty in the United States.

These findings offer both patients and physicians insight into the current stem-cell market for knee osteoarthritis. We hope that with this information, providers can more optimally make patients aware of discrepancies between what is being marketed, versus the current evidence-based landscape of these therapies for knee osteoarthritis.

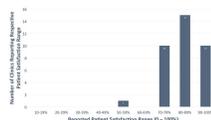
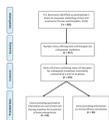


Table 1. Pricing information for stem cell therapies marketed to consumers in the U.S.

U.S. Stem Cell Clinics providing pricing information for same-day unilateral knee injection (n=65)	Statistics
Average Cost	\$5,156
Standard Deviation	\$2,446
Margin of Error	\$606
95% CI	(\$4,550 - \$5,762)
Price Range (Min - Max)	(\$1,150 - \$12,000)

Table 2. Patient Satisfaction Information of Stem Cell Therapies Marketed to Consumers for Knee Osteoarthritis in the U.S.

U.S. Stem Cell Clinics providing clinical efficacy information for same-day knee injection (n=36)	Statistics
Reported Patient Satisfaction	82.2%
Standard Deviation	9.6%
Margin of Error	3.2%
95% CI	(79.0 - 85.5%)
Patient Satisfaction Range (Min - Max)	(55.0% - 100.0%)