

4th HEPATITIS C
TECHNICAL ADVISORY
GROUP
TAG Meeting

SIMPLIFICATION OF PRETREATMENT DIAGNOSTIC EVALUATION AND ON- TREATMENT MONITORING PROCEDURES WITHIN HCV ELIMINATION PROJECT

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28.11.2018

Background

- One of the main aim of HCV Elimination Project – diagnosis and treatment of HCV.
- Even in setting of SOF/LDV availability – management algorithm can be simplified.

Aims

- **Primary aims:**

- Reduce the patient's unnecessary clinical visits.
- Remove the unnecessary laboratory investigations.
- Reduce the financial expanses per patient.
- Reduce the budget of the Project.

- **Secondary aims:**

- Simplified algorithm should not influence on the treatment outcome.
- Make participation in HCV Elimination Project more comfortable.

Methods

- **Location: medical center Mrcheveli & clinic Neolab.**
- **Patient enrollment time: March - May, 2018.**
- **Pre-Treatment simplification.**
- **On-Treatment simplification according treatment regimens.**
- **Control group: patients managed by national guidelines during study period.**
- **Satisfactory questionnaire filled at the end of treatment (EOT) for both groups.**

RBV-containing 12 week regimen

Procedures	Pre-treatment	2	4	6	8	10	12	Follow Up
Drug Control		X	X	X	X	X	X	
Physicians Consultation	XX		X		X		X	X
PCR / HCVcAg	X		X					X
HCV Genotype	X							
CBC	X		X		X		X	
ALT	X		X		X		X	
AST	X							
Creatinine	X						X	
Bil (tot.)	X						X	
Bil (dir.)	X						X	
Albumin	X							
PT, INR	X							
ALP	X							
GGT	X							
Glucose (f.)	X							
HBsAg, anti-HBc (tot)	X							
Ultrasound	X							
Fibroscan	If needed							

RBV-containing 12 week regimen (simplified)

Procedures	Pre-treatment	2	4	6	8	10	12	Follow Up
Drug Control		X	X	X	X	X	X	
Physicians Consultation	XX		X		X		X	X
PCR / HCVcAg	X		X					X
HCV Genotype	X							
CBC	X		X		X		X	
ALT	X		X		X		X	
AST	X							
Creatinine	X						X	
Bil (tot.)	X						X	
Bil (dir.)	X						X	
Albumin	X							
PT, INR	X							
ALP	X							
GGT	X							
Glucose (f.)	X							
HBsAg, anti-HBc (tot)	X							
Ultrasound	X							
Fibroscan	If needed							

RBV-free 12 week regimen

Procedures	Pre-treatment	2	4	6	8	10	12	Follow Up
Drug Control		X	X	X	X	X	X	
Physicians Consultation	XX		X		X		X	X
PCR / HCVcAg	X		X					X
HCV Genotype	X							
CBC	X		X		X		X	
ALT	X		X		X		X	
AST	X							
Creatinine	X						X	
Bil (tot.)	X						X	
Bil (dir.)	X						X	
Albumin	X							
PT, INR	X							
ALP	X							
GGT	X							
Glucose (f.)	X							
HBsAg, anti-HBc (tot)	X							
Ultrasound	X							
Fibroscan	If needed							

RBV-free 12 week regimen (simplified)

Procedures	Pre-treatment	2	4	6	8	10	12	Follow Up
Drug Control		X	X	X	X	X	X	
Physicians Consultation	XX		X		X		X	X
PCR / HCVcAg	X		X					X
HCV Genotype	X							
CBC	X		X		X		X	
ALT	X		X		X		X	
AST	X							
Creatinine	X						X	
Bil (tot.)	X						X	
Bil (dir.)	X						X	
Albumin	X							
PT, INR	X							
ALP	X							
GGT	X							
Glucose (f.)	X							
HBsAg, anti-HBc (tot)	X							
Ultrasound	X							
Fibroscan	If needed							

RBV-containing 24 week regimen

Procedures	Pre-treatment	2	4	6	8	10	12	14	16	18	20	22	24	Follow Up
Drug Control		X	X	X	X	X	X	X	X	X	X	X	X	
Consultation	XX		X		X		X						X	X
PCR/HCVcAg	X		X											X
HCV Genotype	X													
CBC	X		X		X		X						X	
ALT	X		X		X		X						X	
AST	X													
Creatinine	X						X		X		X		X	
Bil (tot.)	X						X						X	
Bil (dir.)	X						X						X	
Albumin	X													
PT, INR	X													
ALP	X													
GGT	X													
Glucose (f.)	X													
HBsAg, anti-HBc	X													
Ultrasound	X													
Fibroscan	If needed													

RBV-containing 24 week regimen (simplified)

Procedures	Pre-treatment	2	4	6	8	10	12	14	16	18	20	22	24	Follow Up
Drug Control		X	X	X	X	X	X	X	X	X	X	X	X	
Consultation	XX		X		X		X						X	X
PCR/HCVcAg	X		X											X
HCV Genotype	X													
CBC	X		X		X		X						X	
ALT	X		X		X		X						X	
AST	X													
Creatinine	X						X		X		X		X	
Bil (tot.)	X						X						X	
Bil (dir.)	X						X						X	
Albumin	X													
PT, INR	X													
ALP	X													
GGT	X													
Glucose (f.)	X													
HBsAg, anti-HBc	X													
Ultrasound	X													
Fibroscan	If needed													

RBV-free 24 week regimen

[illegible]

RBV-free 24 week regimen (simplified)

[illegible]

Satisfactory questionnaire

14	Ease to understand what the doctor said (the doctor explained medical terms)					
15	Overall, the doctor's consultations during the visits					
16	Ease in obtaining diagnostic test results					
17	Preparation of medical documentations by the clinic for program enrollment					
18	Convenience of procedures related to the registration in HCV elimination program					
19	Convenience of procedures related to the treatment in HCV elimination program					

20. Approximately how much money (GEL) have you spent out of pocket for HCV treatment service at this clinic?
☐ Fees ----- (GEL) ☐ Travel cost ----- (GEL) ☐ other costs ----- (GEL) (specify) -----

21. How many days of work (if any) have you had to miss to attend appointments related to HCV treatment program at this clinic?

☐ Number of days ----- ☐ N/A (I don't work)

What would you change/improve in HCV elimination program? -----

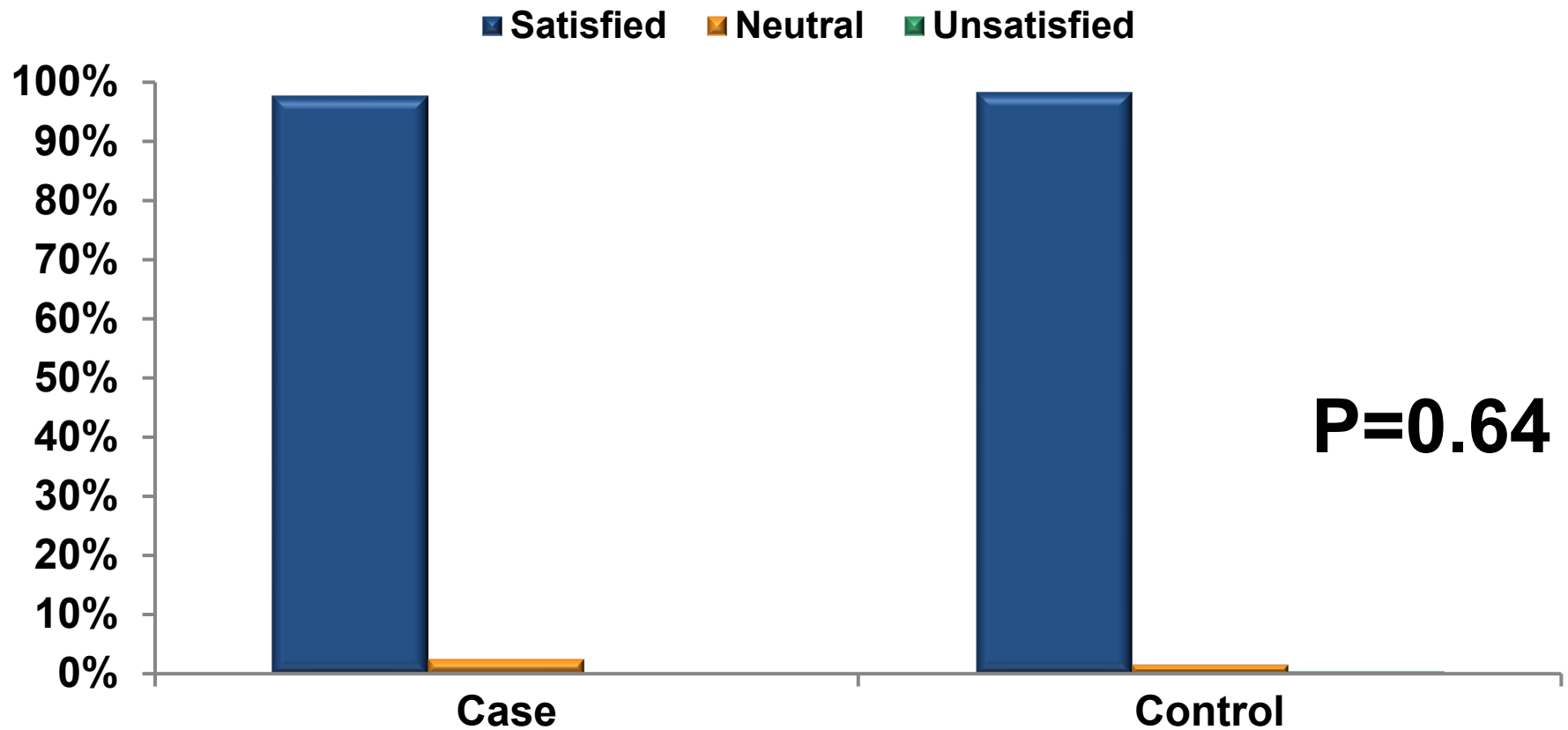
22. Would you recommend the HCV treatment service you received at this clinic to your friends or family?

1. Yes
2. No
3. Not sure

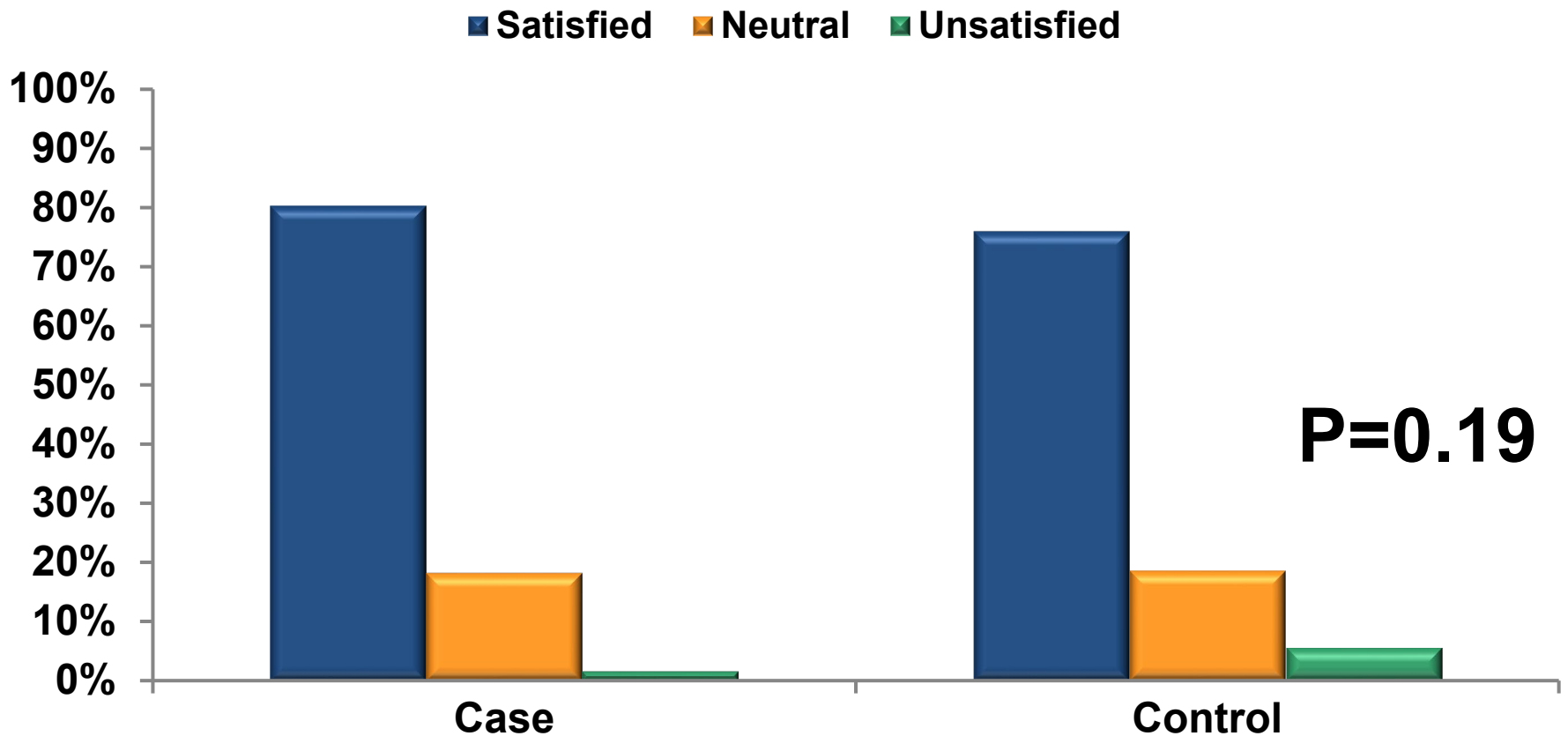
Preliminary Results

Demographics	Case	Control	P value
Number	127	275	
Sex			
• Male	64.6%	75.6%	0.21
• Female	35.4%	24.4%	
Age			
• <35	18.9%	13.5%	0.01
• 35-55	51.6%	67.8%	
• >55	29.5%	18.8%	
Liver damage			
• FIB 4 <1.45/LE <F3	75.2%	68.7%	0.2
• FIB 4 >3.25/LE – F3/4	24.8%	31.3%	

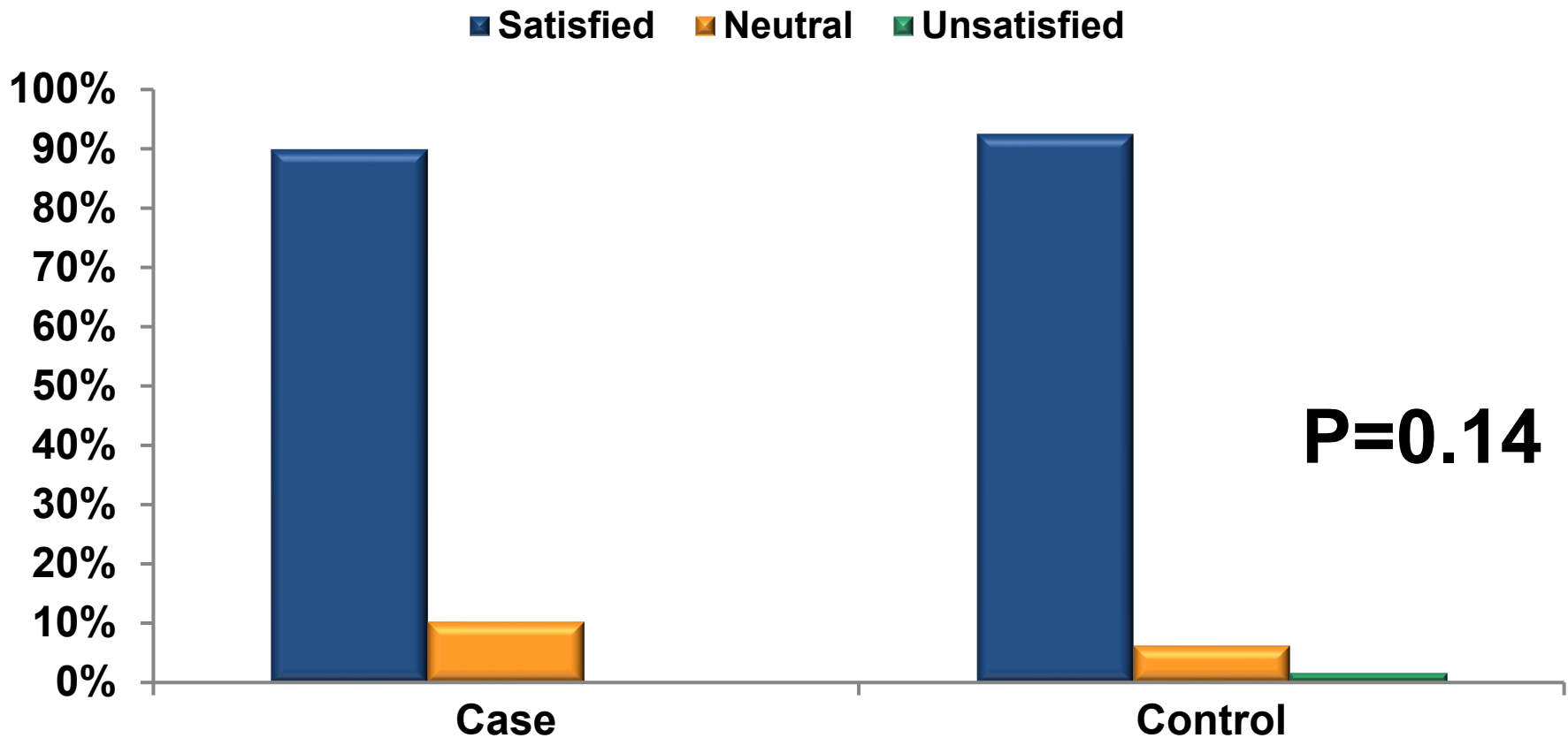
Q1 - Overall service that you've received at our clinic



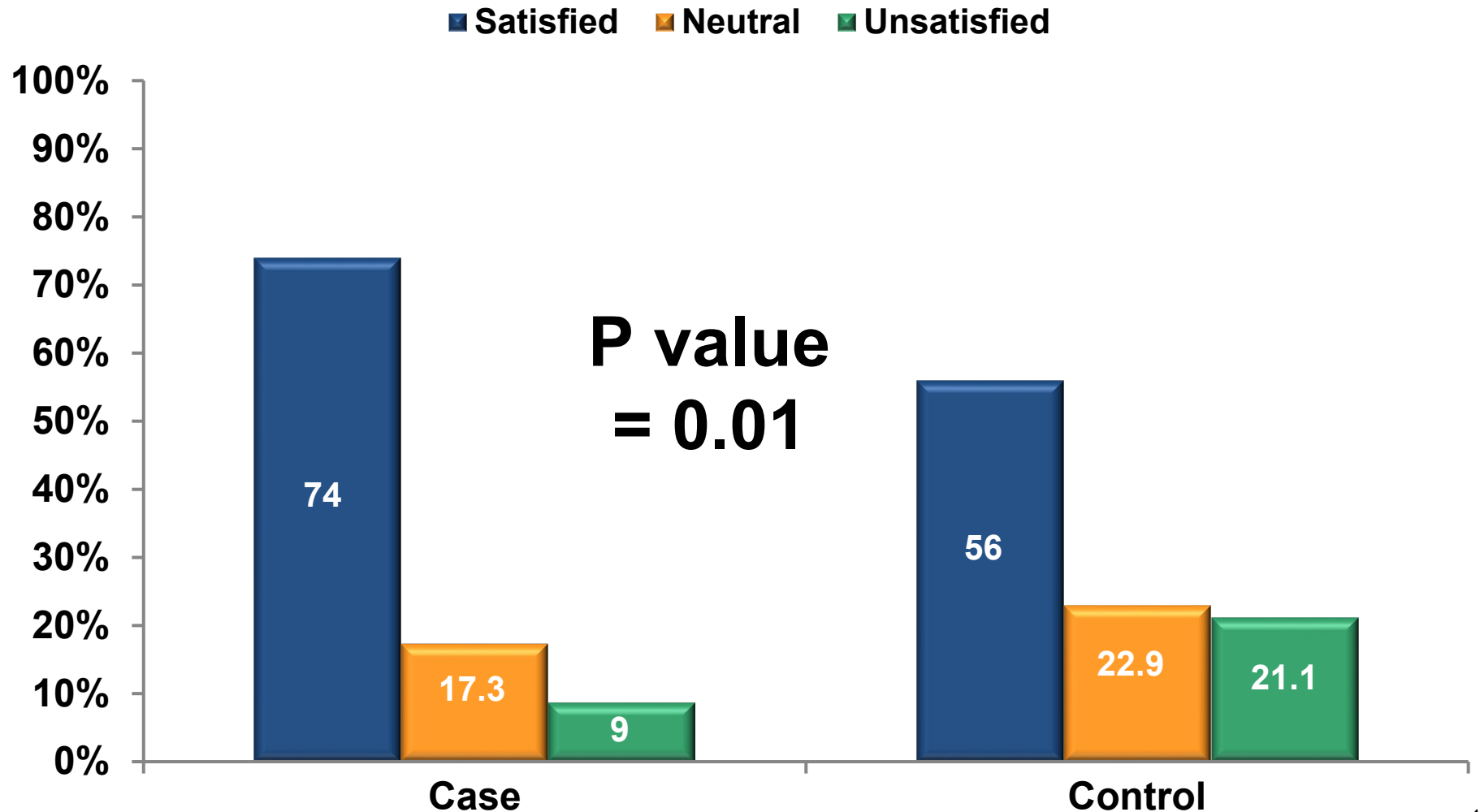
Q2 - Convenience of our clinic in terms of location



Q3 - Convenience of office hours when you received medical service at our clinic

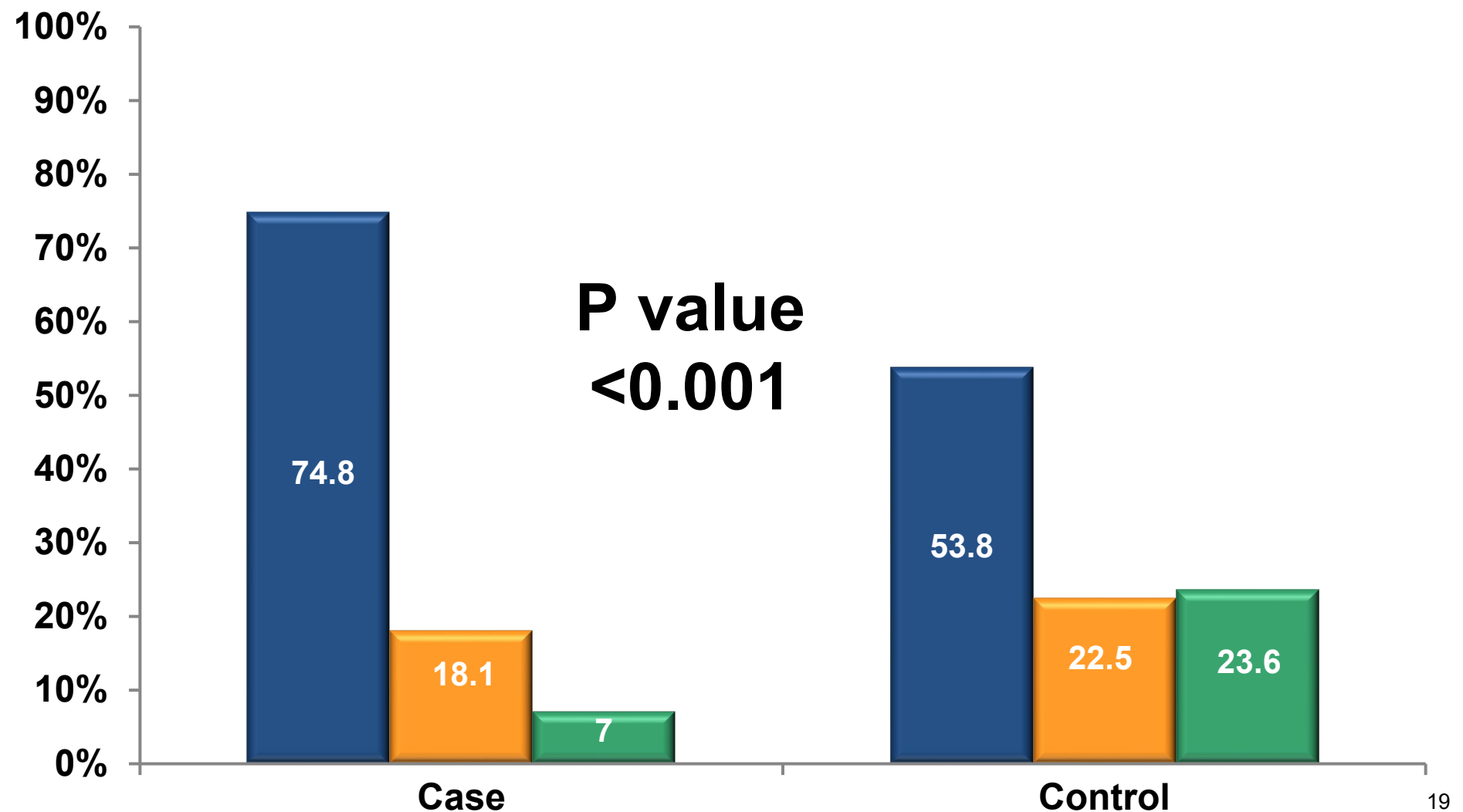


Q4 - Cost of pre-treatment diagnostic tests

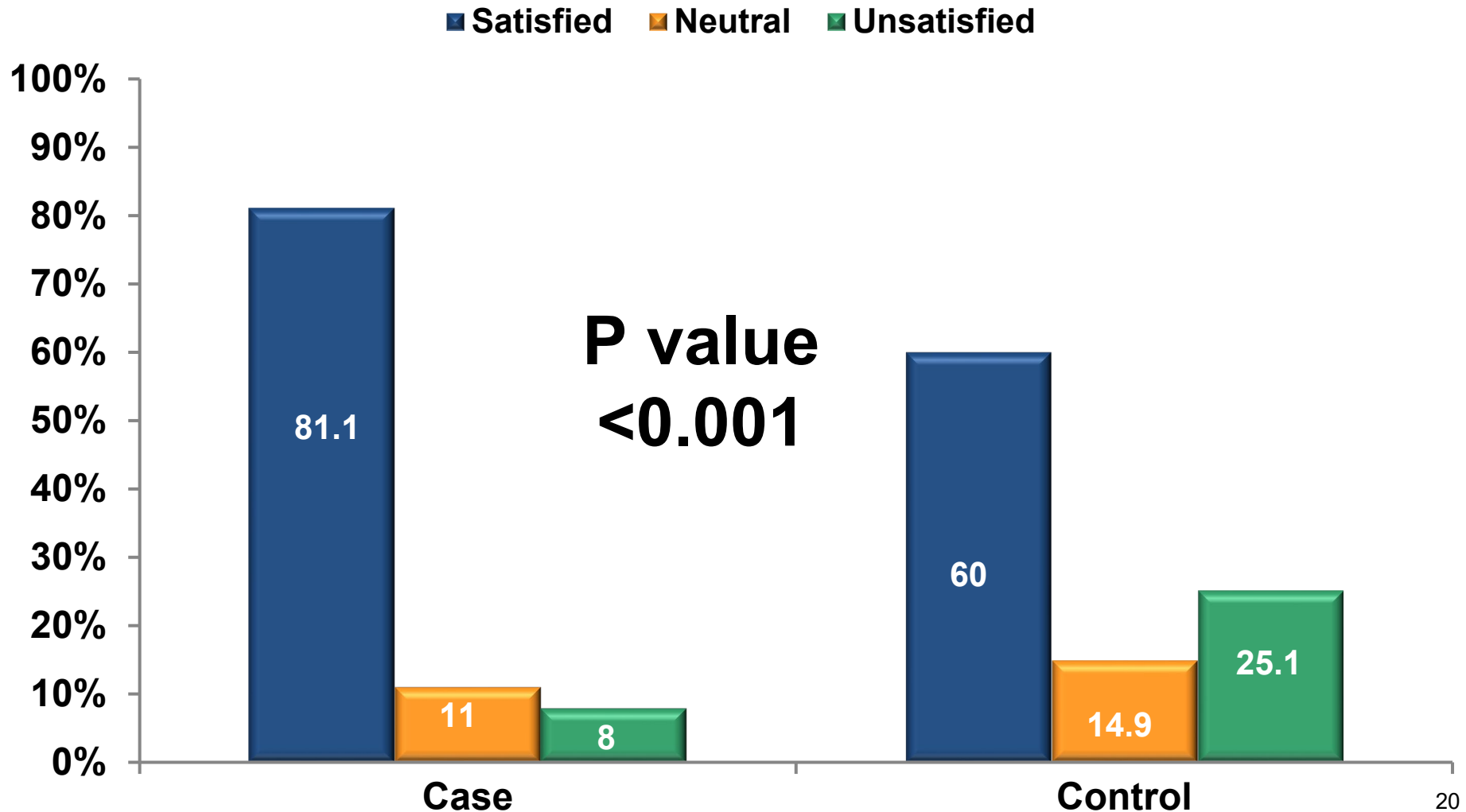


Q5 - Cost of on-treatment diagnostic tests

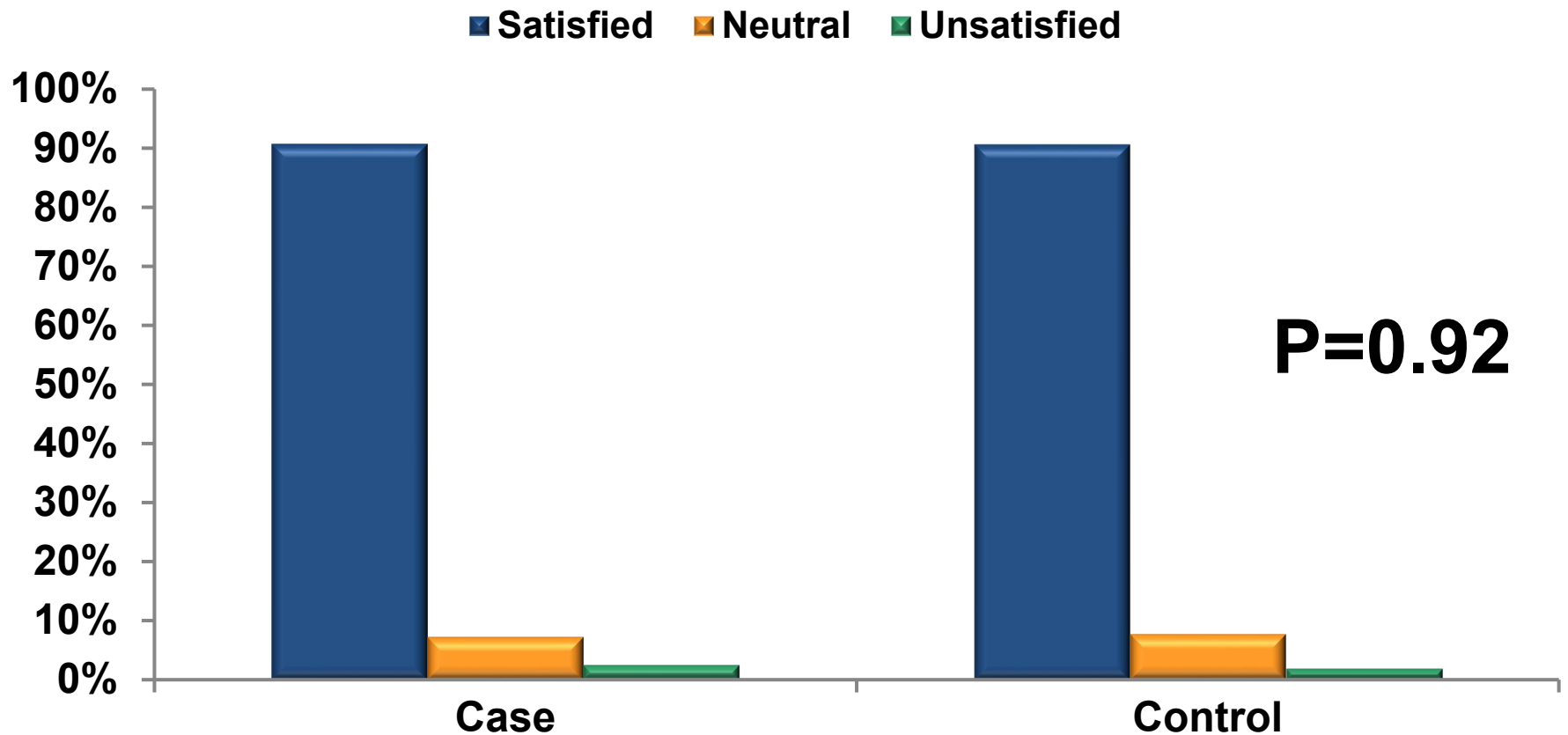
■ Satisfied ■ Neutral ■ Unsatisfied



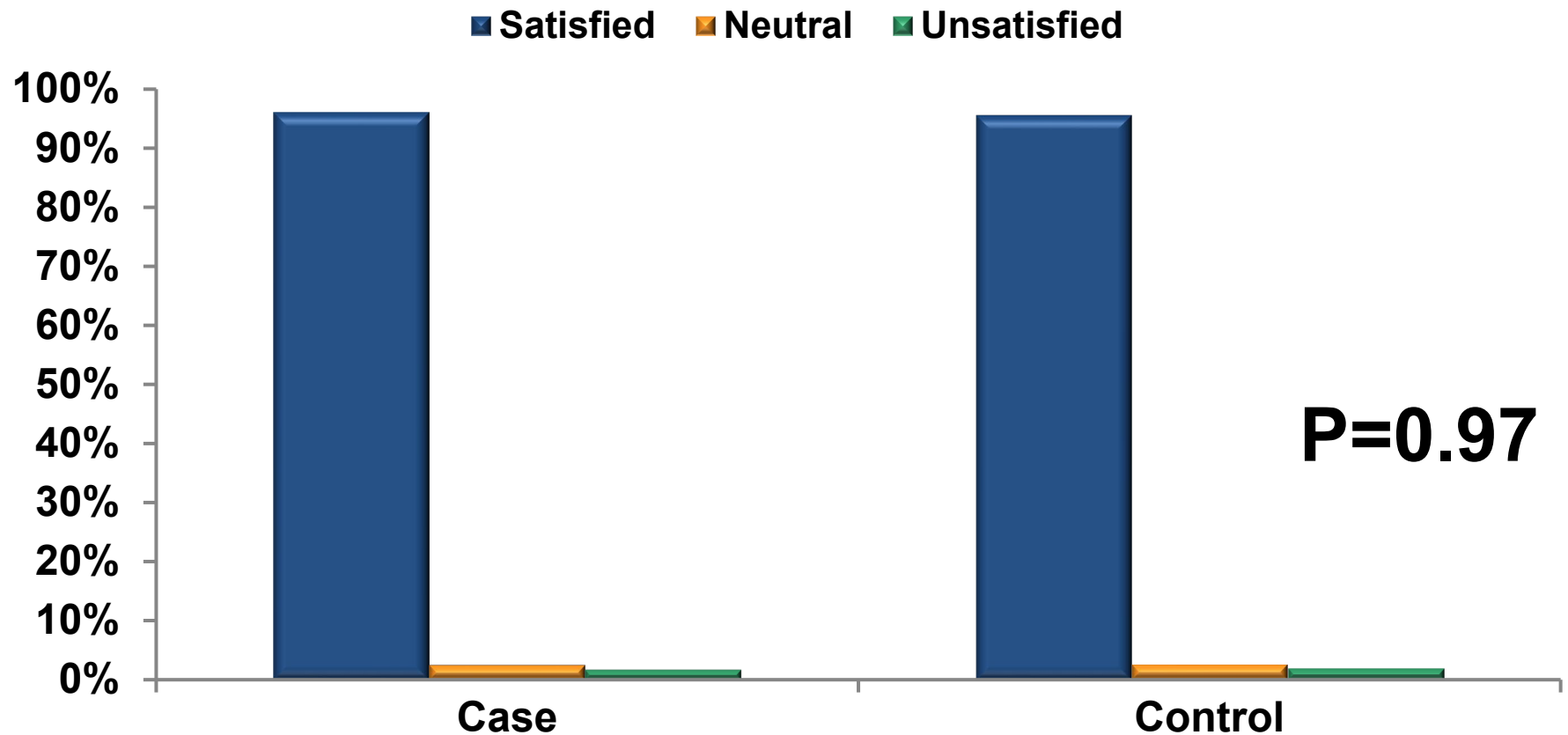
Q6 - Number of visits at the clinic



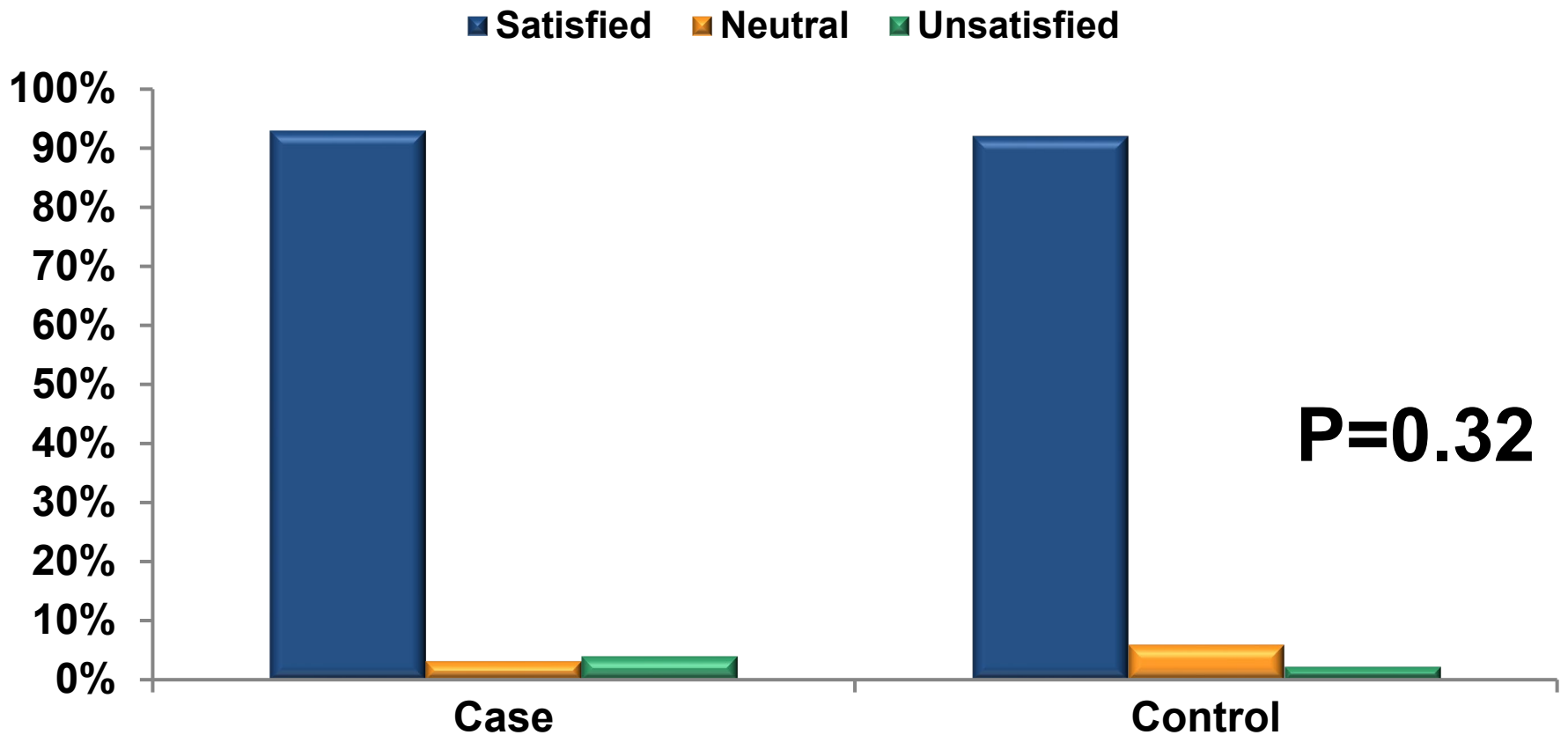
Q7 - Waiting time during the visits at the clinic



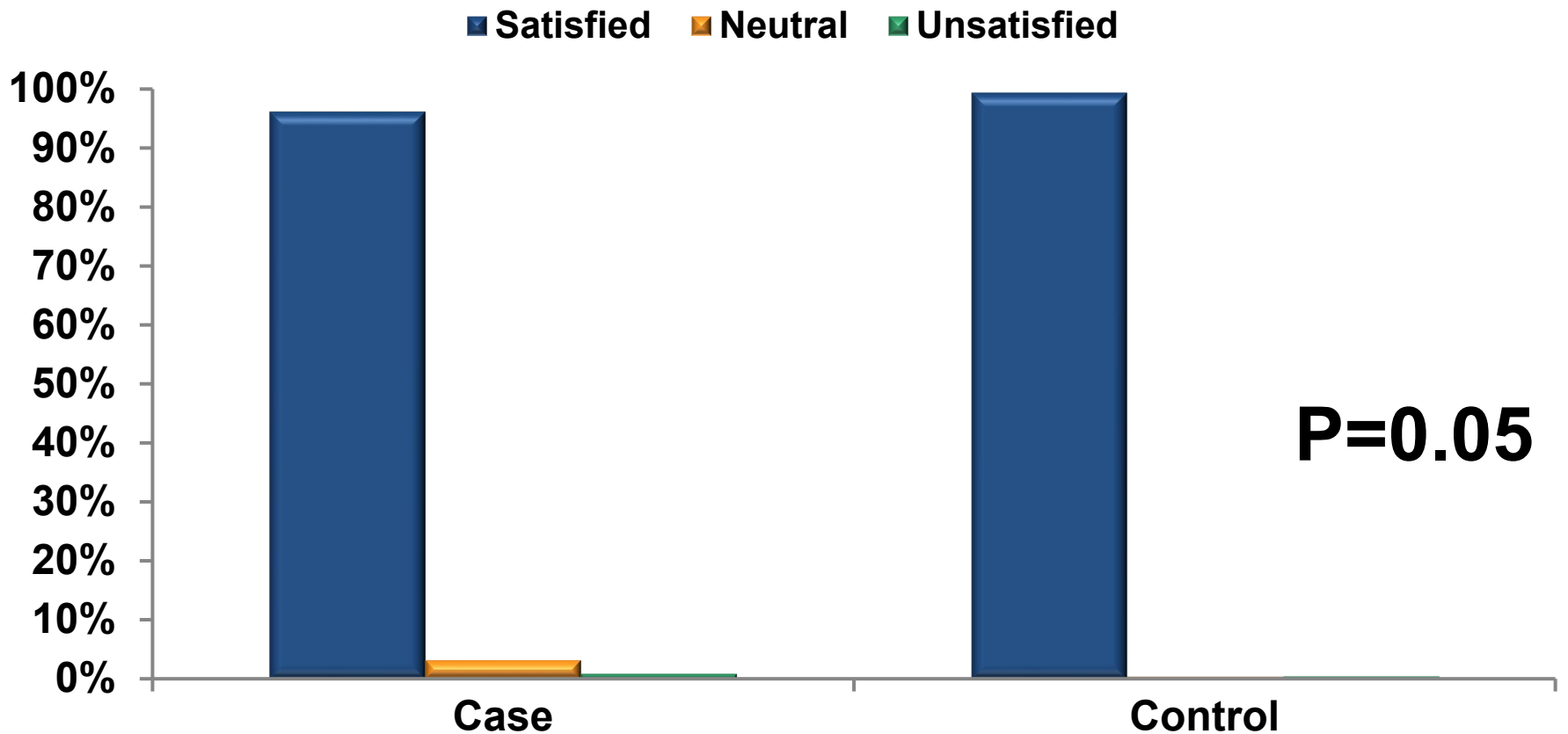
Q8 - Time that doctor spent with you during the visits



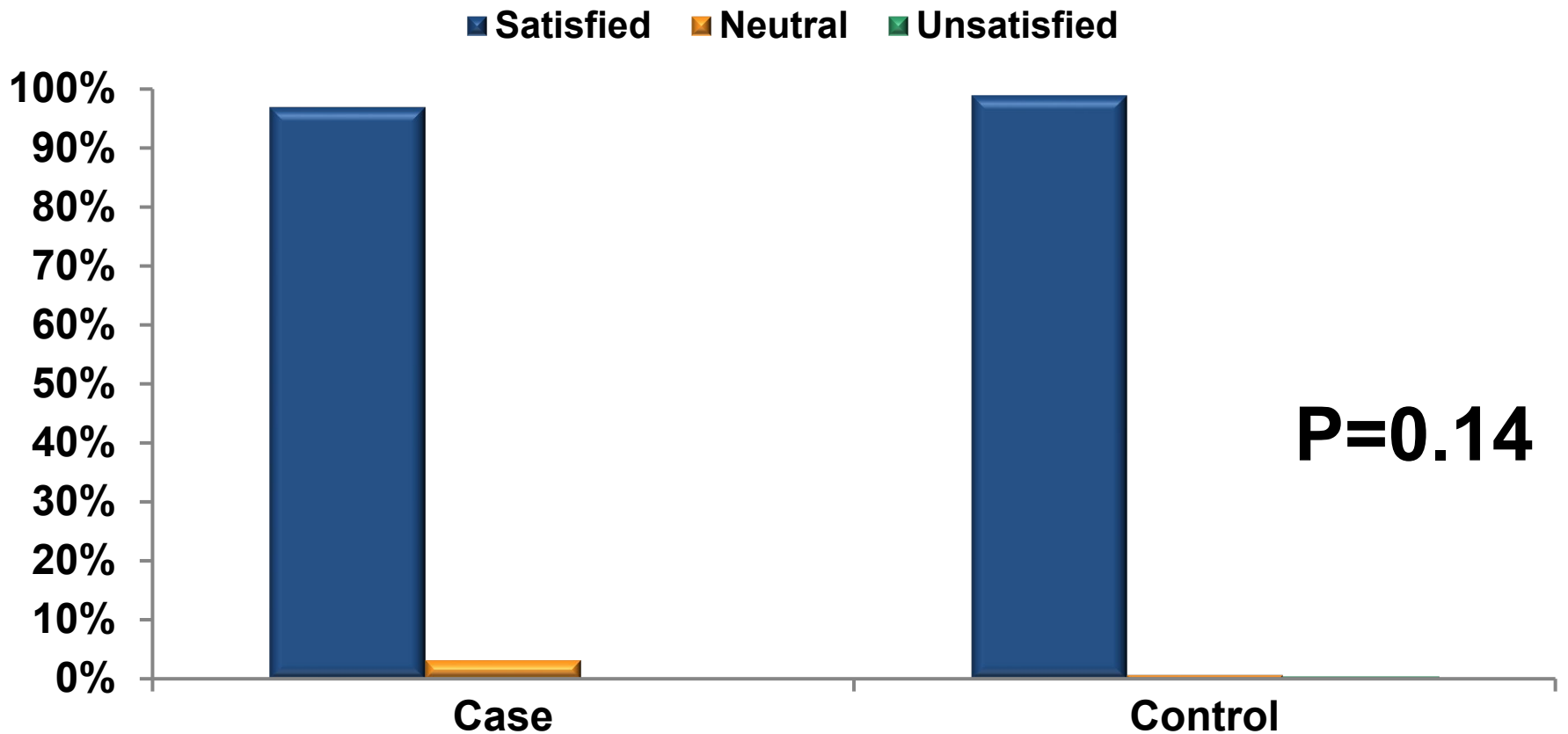
Q9 - Time that you spent during medical procedures



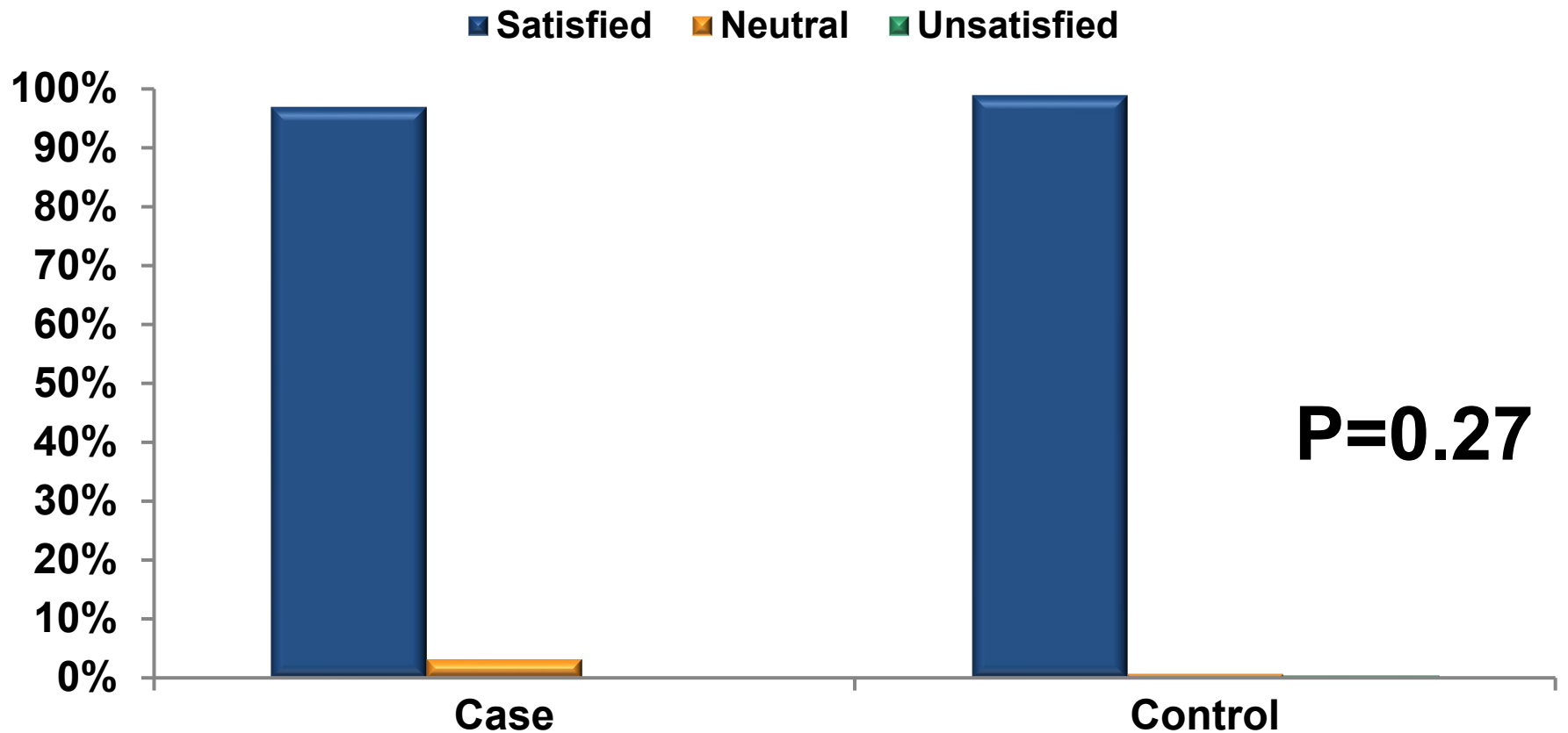
Q10 - The doctor's explanations about the reasons of diagnostic tests



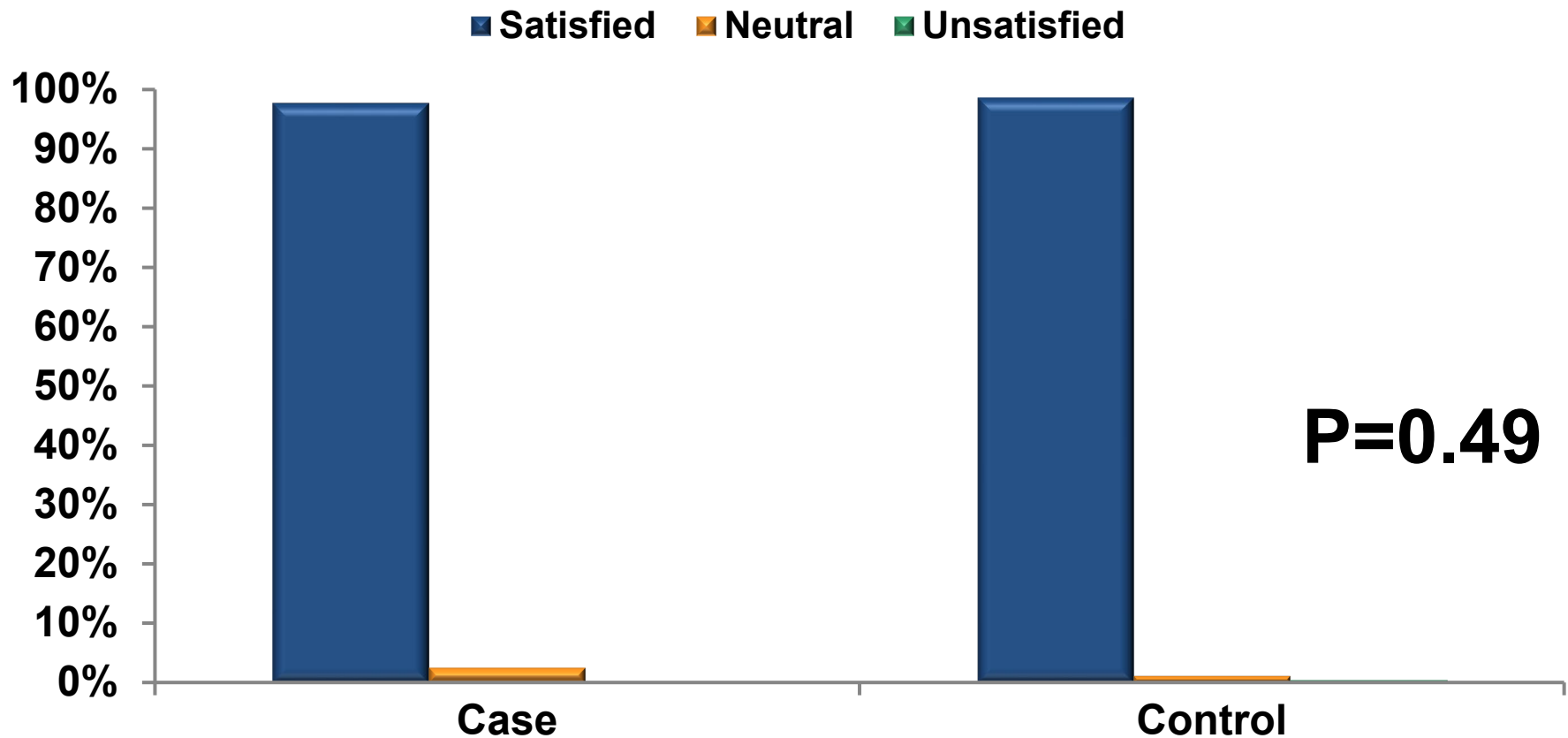
Q11 - The doctor's explanations about the results of diagnostic tests



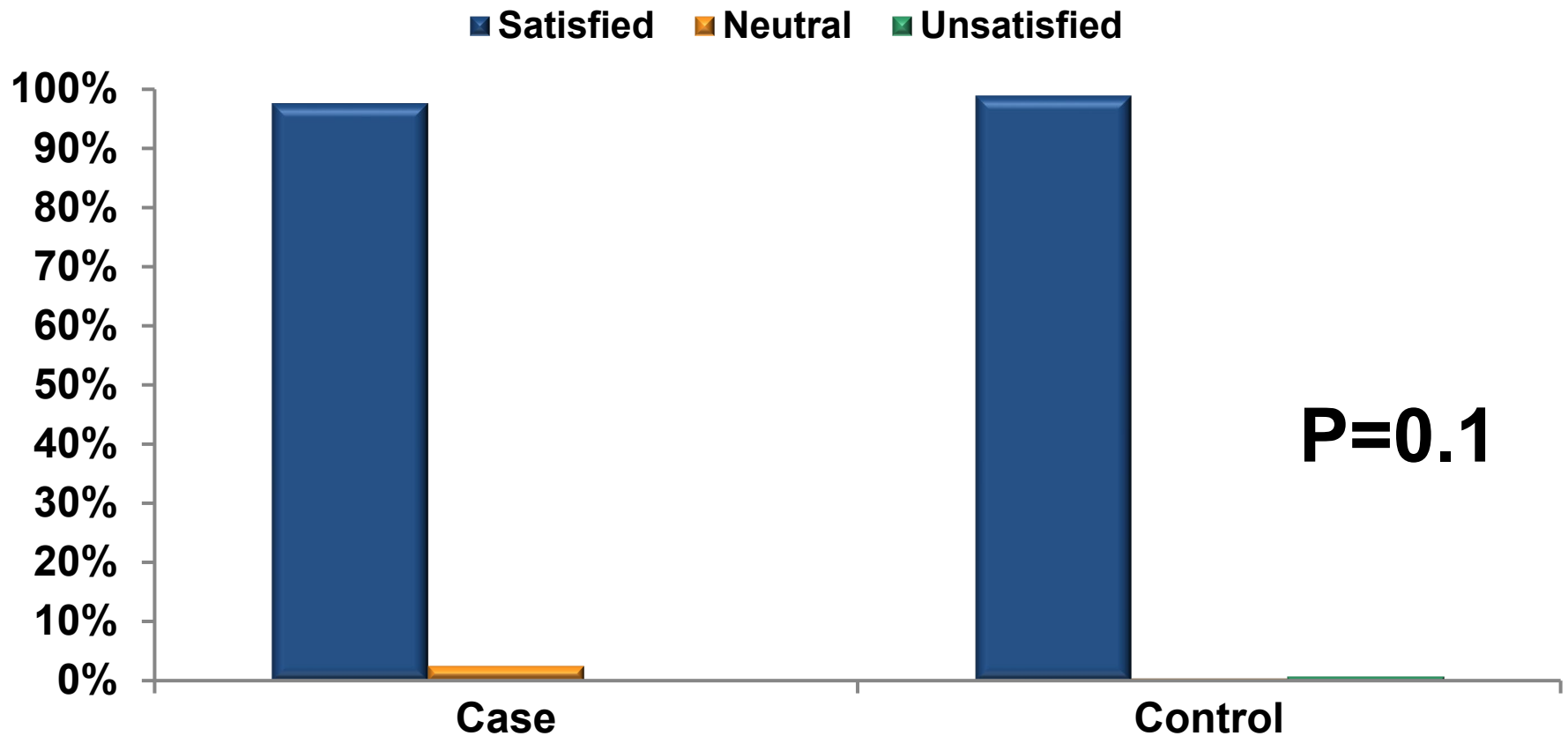
Q12 - The doctor's instructions how to take medicine(s)



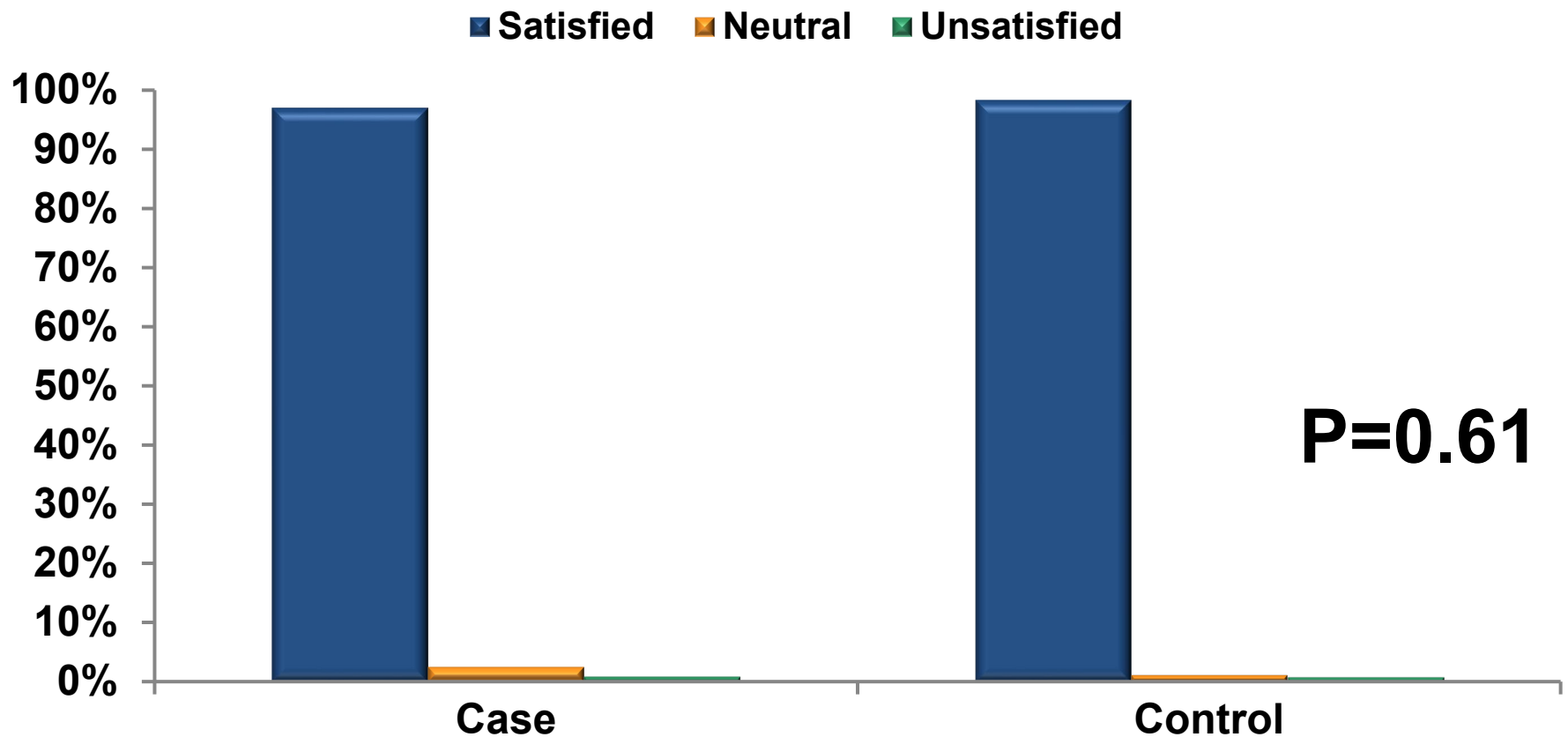
Q13 - Ease to communicate with the doctor during the visits (I was allowed to say everything that I thought was important)



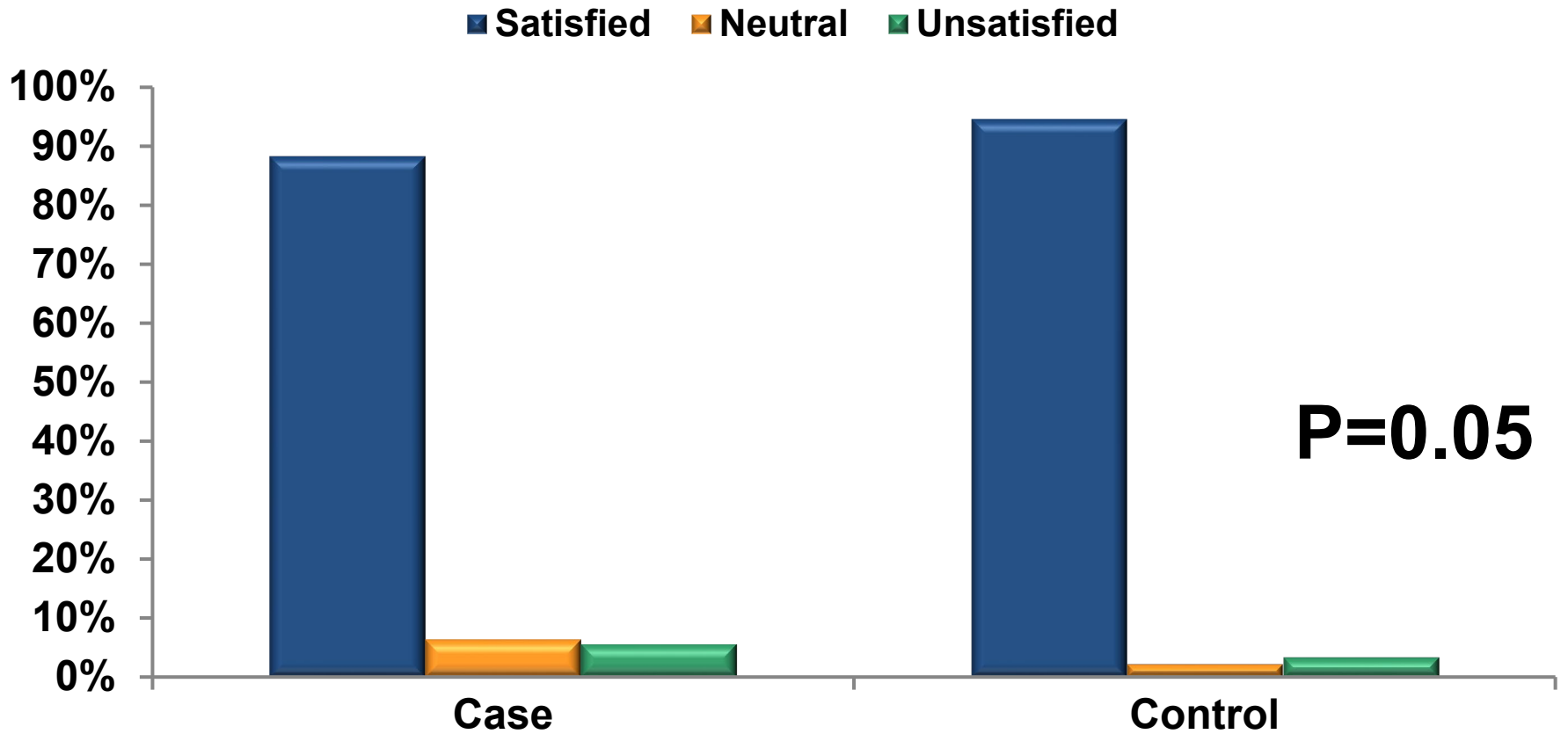
Q14 - Ease to understand what the doctor said (the doctor explained medical terms)



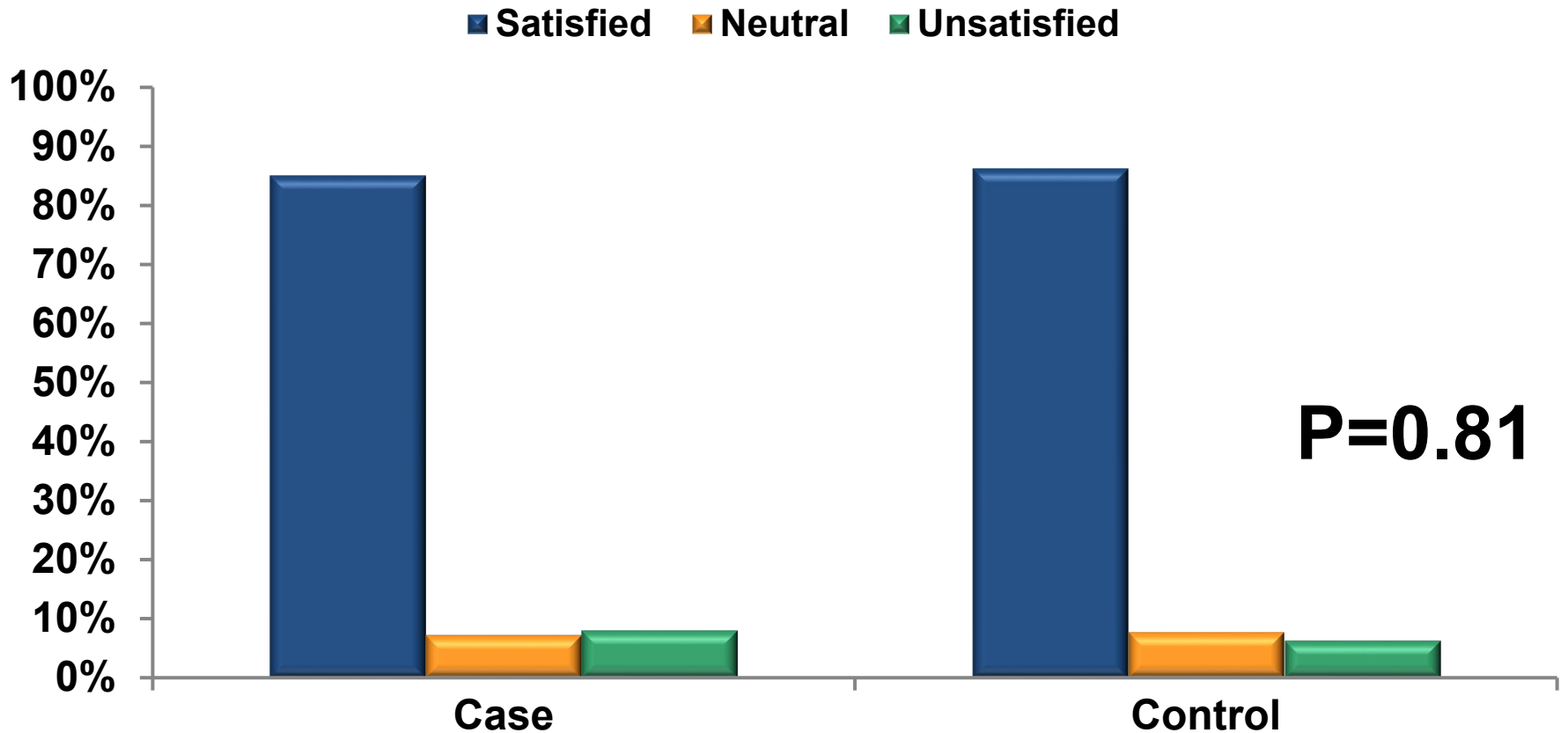
Q15 - Overall, the doctor's consultations during the visits



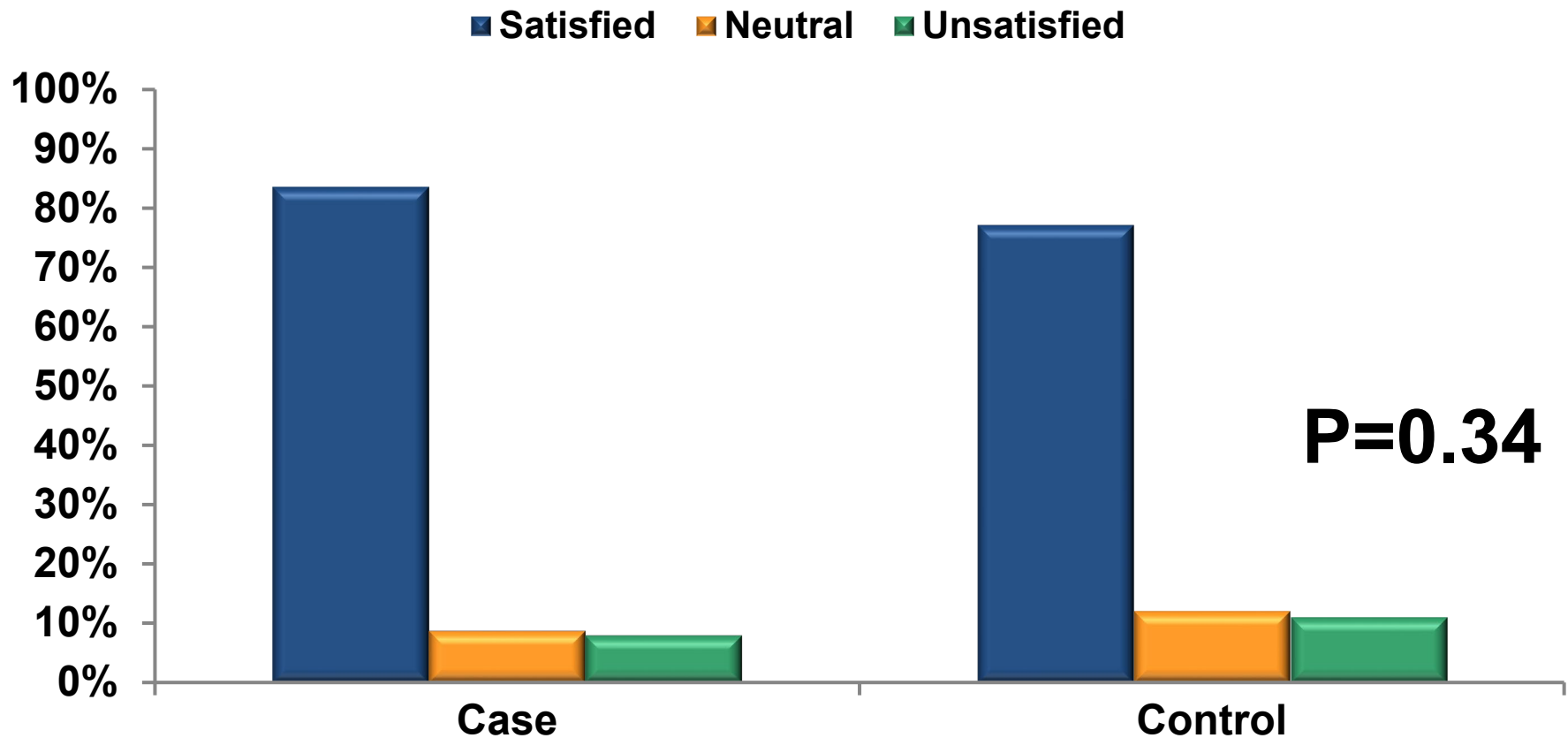
Q16 - Ease in obtaining diagnostic test results



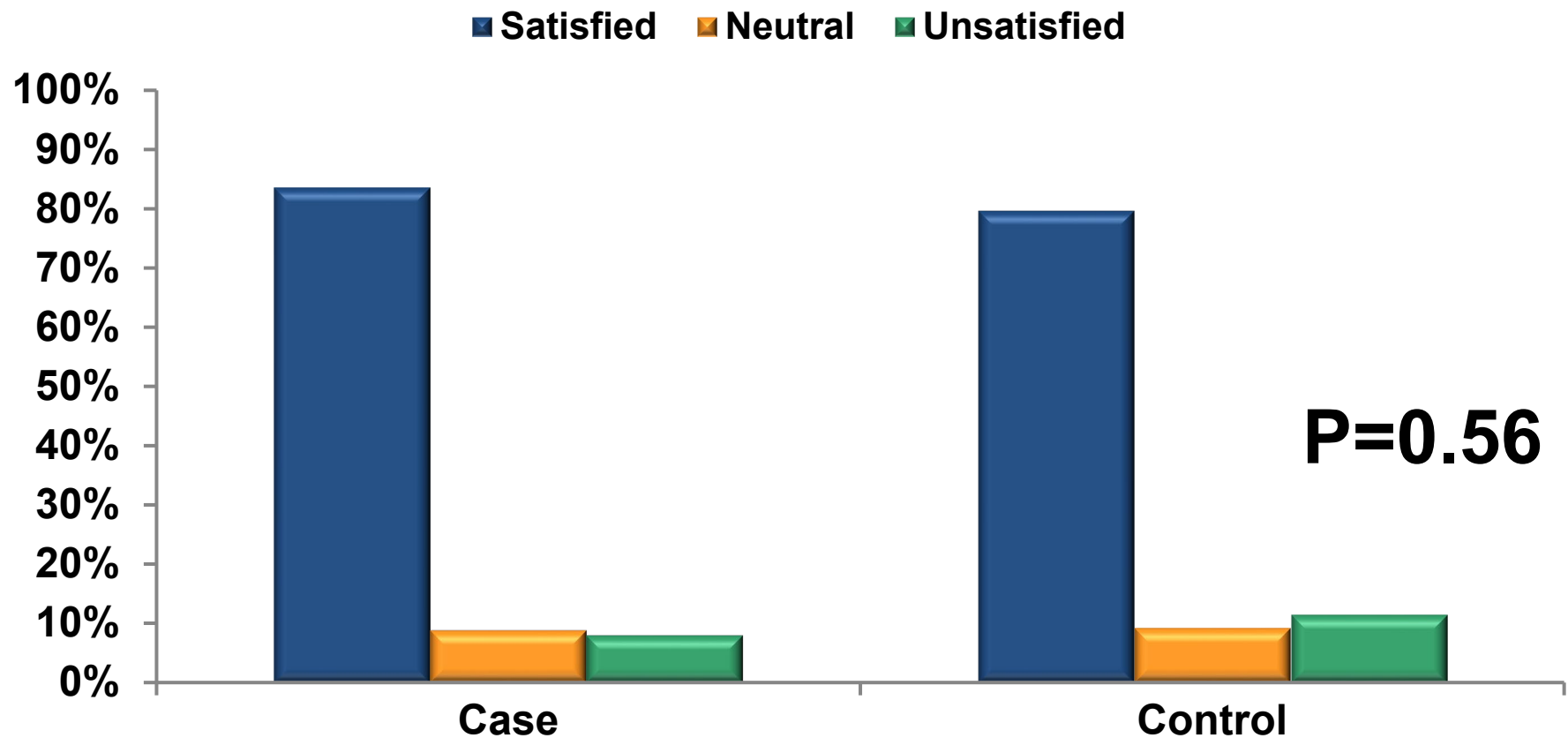
Q17 - Preparation of medical documentations by the clinic for program enrollment



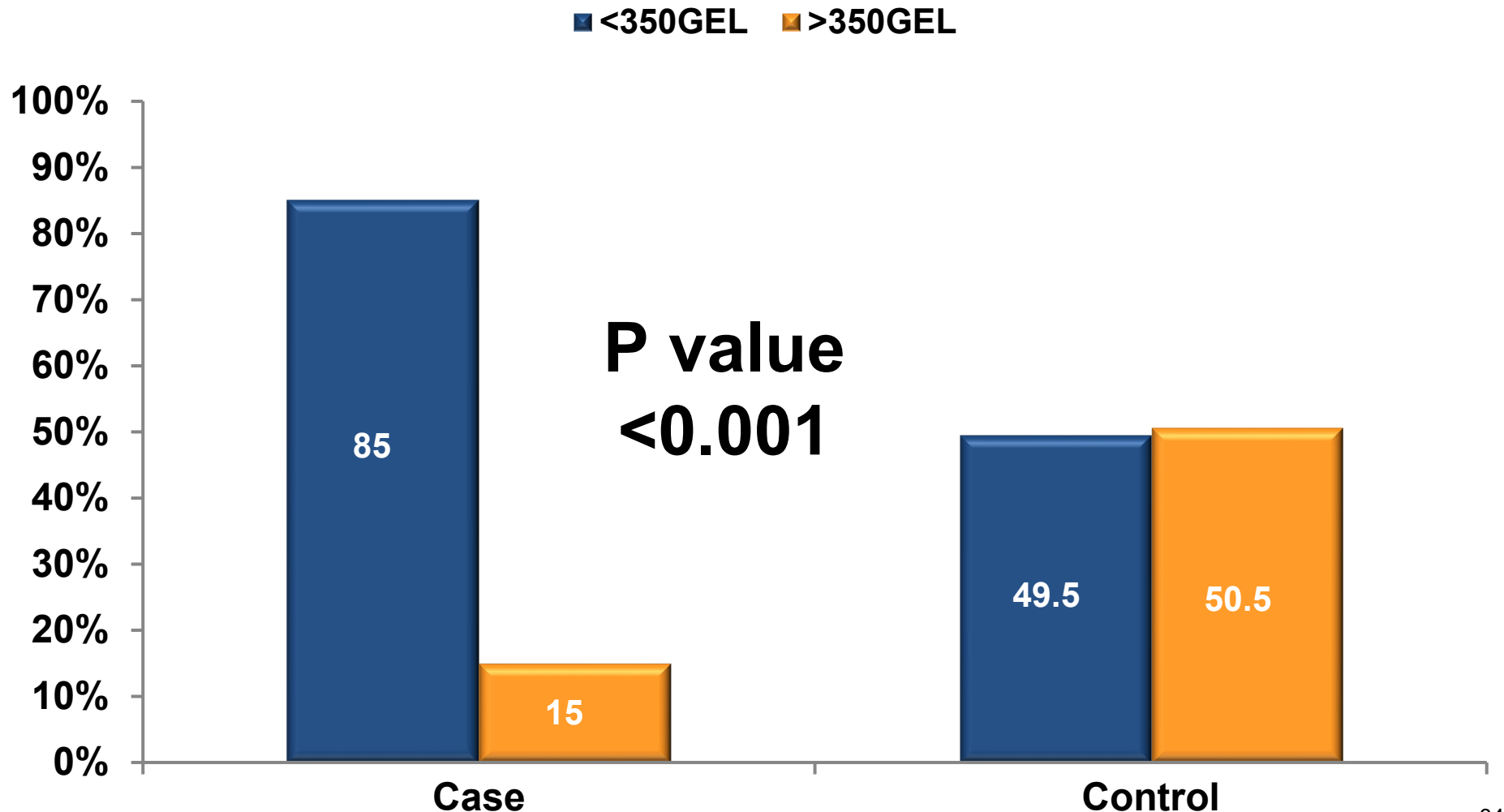
Q18 - Convenience of procedures related to the registration in HCV elimination program



Q19 - Convenience of procedures related to the treatment in HCV elimination program



Q20 - Approximately how much money (GEL) have you spent out of pocket for HCV treatment service at this clinic?



Conclusions

- Overall satisfaction rates from HCV Elimination Program are high.
- Costs per patient decreased significantly:
 - Pre-Tx (all) – 289 GEL → 269 GEL
 - Harvoni 12w – 218 GEL → 70 GEL
 - Harvoni/RBV 12w – 227 GEL → 97 GEL
 - Harvoni 24w – 277 GEL → 95 GEL
 - Harvoni/RBV 24w – 286 GEL → 136 GEL
- Patients are satisfied by decreasing frequent visits in treatment sites.
- Final results are pending - SVR rates for case/controls aren't yet collected.